(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
22 February 2001 (22.02.2001)

PCT

(10) International Publication Number
WO 01/12107 A1

(51) International Patent Classification[7]: A61F 2/44

(21) International Application Number: PCT/US00/22907

(22) International Filing Date: 18 August 2000 (18.08.2000)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

60/149,490	18 August 1999 (18.08.1999)	US
60/161,085	25 October 1999 (25.10.1999)	US
60/172,996	21 December 1999 (21.12.1999)	US
09/608,797	30 June 2000 (30.06.2000)	US

(63) Related by continuation (CON) or continuation-in-part (CIP) to earlier applications:

US	09/608,797 (CIP)
Filed on	30 June 2000 (30.06.2000)
US	60/172,996 (CIP)
Filed on	21 December 1999 (21.12.1999)
US	60/161,085 (CIP)
Filed on	25 October 1999 (25.10.1999)
US	60/149,490 (CIP)
Filed on	18 August 1999 (18.08.1999)

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(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

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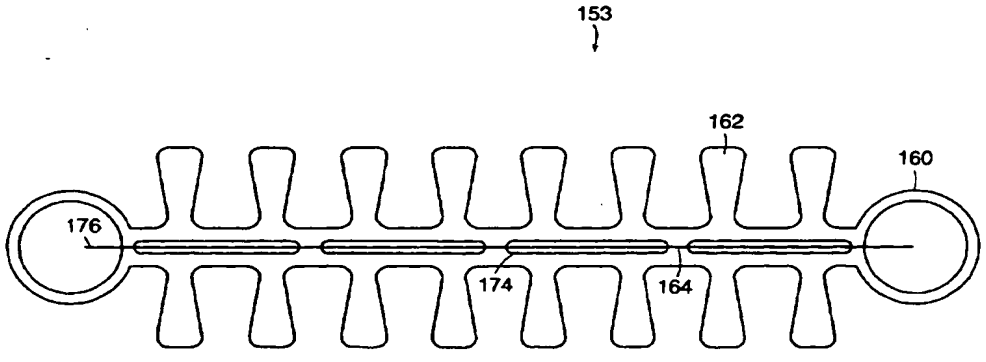
(54) Title: DEVICES AND METHODS OF VERTEBRAL DISC AUGMENTATION



(57) Abstract: Devices for implantation into an intervertebral disc can include a membrane support member to augment a disc having a defect. A defect in the annulus of a disc can be repaired using a prosthesis such as a barrier. The barrier can include a sealant and an enlarger. The barrier can be implanted into the disc using a delivery cannula, an advancer and at least one control filament to control the positioning of the barrier. A stiffening element can be included within the barrier to impart stiffness to the barrier. The support member can also be connected to an anchor.

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DEVICES AND METHODS OF VERTEBRAL DISC AUGMENTATION

RELATED APPLICATION(S)

This application claims the benefit of U.S. Application No. 09/608,797 filed on June 30, 2000, U.S. Provisional Application No. 60/149,490 filed August 18, 1999, U.S. Provisional Application No. 60/161,085 filed October 25, 1999 and U.S. Provisional Application No. 60/172,996 filed December 21, 1999, the entire teachings of these applications being incorporated herein by reference.

BACKGROUND OF THE INVENTION

The present invention relates to the surgical treatment of intervertebral discs in the lumbar, cervical, or thoracic spine that have suffered from tears in the annulus fibrosis, herniation of the nucleus pulposus and/or significant disc height loss.

The disc performs the important role of absorbing mechanical loads while allowing for constrained flexibility of the spine. The disc is composed of a soft, central nucleus pulposus (NP) surrounded by a tough, woven annulus fibrosis (AF). Herniation is a result of a weakening in the AF. Symptomatic herniations occur when weakness in the AF allows the NP to bulge or leak posteriorly toward the spinal cord and major nerve roots. The most common resulting symptoms are pain radiating along a compressed nerve and low back pain, both of which can be crippling for the patient. The significance of this problem is increased by the low average age of diagnosis, with over 80% of patients in the U.S. being under 59.

Since its original description by Mixter & Barr in 1934, discectomy has been the most common surgical procedure for treating intervertebral disc herniation. This

procedure involves removal of disc materials impinging on the nerve roots or spinal cord external to the disc, generally posteriorly. Depending on the surgeon's preference, varying amounts of NP are then removed from within the disc space either through the herniation site or through an incision in the AF. This removal of extra NP is commonly done to minimize the risk of recurrent herniation.

Nevertheless, the most significant drawbacks of discectomy are recurrence of herniation, recurrence of radicular symptoms, and increasing low back pain. Re-herniation can occur in up to 21% of cases. The site for re-herniation is most commonly the same level and side as the previous herniation and can occur through the same weakened site in the AF. Persistence or recurrence of radicular symptoms happens in many patients and when not related to re-herniation, tends to be linked to stenosis of the neural foramina caused by a loss in height of the operated disc. Debilitating low back pain occurs in roughly 14% of patients. All of these failings are most directly related to the loss of NP material and AF competence that results from herniation and surgery.

Loss of NP material deflates the disc, causing a decrease in disc height. Significant decreases in disc height have been noted in up to 98% of operated patients. Loss of disc height increases loading on the facet joints. This can result in deterioration of facet cartilage and ultimately osteoarthritis and pain in this joint. As the joint space decreases the neural foramina formed by the inferior and superior vertebral pedicles also close down. This leads to foraminal stenosis, pinching of the traversing nerve root, and recurring radicular pain. Loss of NP also increases loading on the remaining AF, a partially innervated structure that can produce pain. Finally, loss of NP results in greater bulging of the AF under load. This can result in renewed impingement by the AF on nerve structures posterior to the disc.

Persisting tears in the AF that result either from herniation or surgical incision also contribute to poor results from discectomy. The AF has limited healing capacity with the greatest healing occurring in its outer borders. Healing takes the form of a thin fibrous film that does not approach the strength of the uninjured disc. Surgical incision in the AF has been shown to produce immediate and long lasting decreases in stiffness of the AF particularly against torsional loads. This may over-

stress the facets and contribute to their deterioration. Further, in as many as 30% of cases, the AF never closes. In these cases, not only is re-herniation a risk but also leakage of fluids or solids from within the NP into the epidural space can occur. This has been shown to cause localized pain, irritation of spinal nerve roots, decreases in nerve conduction velocity, and may contribute to the formation of post-surgical scar tissue in the epidural space.

Other orthopedic procedures involving removal of soft tissue from a joint to relieve pain have resulted in significant, long lasting consequences. Removal of all or part of the menisci of the knee is one example. Partial and total meniscectomy leads to increased osteoarthritic degeneration in the knee and the need for further surgery in many patients. A major effort among surgeons to repair rather than resect torn menisci has resulted in more durable results and lessened joint deterioration.

Systems and methods for repairing tears in soft tissues are known in the art. One such system relates to the repair of the menisci of the knee and is limited to a barbed tissue anchor, an attached length of suture, and a suture-retaining member, which can be affixed to the suture and used to draw the sides of a tear into apposition. The drawback of this method is that it is limited to the repair of a tear in soft tissue. In the intervertebral disc, closure of a tear in the AF does not necessarily prevent further bulging of that disc segment toward the posterior neural elements. Further, there is often no apparent tear in the AF when herniation occurs. Herniation can be a result of a general weakening in the structure of the AF (soft disc) that allows it to bulge posteriorly without a rupture. When tears do occur, they are often radial.

Another device known in the art is intended for repair of a tear in a previously contiguous soft tissue. Dart anchors are placed across the tear in a direction generally perpendicular to the plane of the tear. Sutures leading from each of at least two anchors are then tied together such that the opposing sides of the tear are brought together. However, all of the limitations pertaining to repair of intervertebral discs, as described above, pertain to this device.

Also known in the art is an apparatus and method of using tension to induce growth of soft tissue. The known embodiments and methods are limited in their

application to hernias of the intervertebral disc in that they require a spring to apply tension. Aside from the difficulty of placing a spring within the limited space of the intervertebral disc, a spring will induce a continuous displacement of the attached tissues that could be deleterious to the structure and function of the disc. A spring may further allow a posterior bulge in the disc to progress should forces within the disc exceed the tension force applied by the spring. Further, the known apparatus is designed to be removed once the desired tissue growth has been achieved. This has the drawback of requiring a second procedure.

There are numerous ways of augmenting the intervertebral disc disclosed in the art. In reviewing the art, two general approaches are apparent - implants that are fixed to surrounding tissues and those that are not fixed, relying instead on the AF to keep them in place.

The first type of augmenting of the intervertebral disc includes generally replacing the entire disc. This augmentation is limited in many ways. First, by replacing the entire disc, they generally must endure all of the loads that are transferred through that disc space. Many degenerated discs are subject to pathologic loads that exceed those in normal discs. Hence, the designs must be extremely robust and yet flexible. None of these augmentation devices has yet been able to achieve both qualities. Further, devices that replace the entire disc must be implanted using relatively invasive procedures, normally from an anterior approach. They may also require the removal of considerable amounts of healthy disc material including the anterior AF. Further, the disclosed devices must account for the contour of the neighboring vertebral bodies to which they are attached. Because each patient and each vertebra is different, these types of implants must be available in many shapes and sizes.

The second type of augmentation involves an implant that is not directly fixed to surrounding tissues. These augmentation devices rely on an AF that is generally intact to hold them in place. The known implants are generally inserted through a hole in the AF and either expand, are inflated, or deploy expanding elements so as to be larger than the hole through which they are inserted. The limitation of these concepts is that the AF is often not intact in cases requiring

augmentation of the disc. There are either rents in the AF or structural weaknesses that allow herniation or migration of the disclosed implants. In the case of a disc herniation, there are definite weaknesses in the AF that allowed the herniation to occur. Augmenting the NP with any of the known augmentation devices without supporting the AF or implant risks re-herniation of the augmenting materials. Further, those devices with deployable elements risk injuring the vertebral endplates or the AF. This may help to retain the implant in place, but again herniations do not require a rent in the AF. Structural weakness in or delamination of the multiple layers of the AF can allow these implants to bulge toward the posterior neural elements. Additionally, as the disc continues to degenerate, rents in the posterior annulus may occur in regions other than the original operated site. A further limitation of these concepts is that they require the removal of much or all of the NP to allow insertion of the implant. This requires time and skill to achieve and permanently alters the physiology of the disc.

Implanting prostheses in specific locations within the intervertebral disc is also a challenging task. The interior of the disc is not visible to the surgeon during standard posterior spinal procedures. Very little of the exterior of the disc can be seen through the small window created by the surgeon in the posterior elements of the vertebrae to gain access to the disc. The surgeon further tries to minimize the size of any annular fenestration into the disc in order to reduce the risk of postoperative herniation and/or further destabilization of the operated level. Surgeons generally open only one side of the posterior annulus in order to avoid scarring on both sides of the epidural space.

The rigorous requirements presented by these limitations on access to and visualization of the disc are not well compensated for by any of the intradiscal prosthesis implantation systems currently available.

The known art relating to the closure of body defects such as hernias through the abdominal wall involve devices such as planer patches applied to the interior of the abdominal wall or plugs that are placed directly into the defect. The known planar patches are limited in their application in the intervertebral disc by the disc's geometry. The interior aspect of the AF is curved in multiple planes, making a flat

patch incongruous to the surface against which it must seal. Finally, the prior art discloses patches that are placed into a cavity that is either distended by gas or supported such that the interior wall of the defect is held away from internal organs. In the disc, it is difficult to create such a cavity between the inner wall of the annulus and the NP without removing nucleus material. Such removal may be detrimental to the clinical outcome of disc repair.

One hernia repair device known in the art is an exemplary plug. This plug may be adequate for treating inguinal hernias, due to the low pressure difference across such a defect. However, placing a plug into the AF that must resist much higher pressures may result in expulsion of the plug or dissection of the inner layers of the annulus by the NP. Either complication would lead to extraordinary pain or loss of function for the patient. Further, a hernia in the intervertebral disc is likely to spread as the AF progressively weakens. In such an instance, the plug may be expelled into the epidural space.

Another hernia repair device involves a curved prosthetic mesh for use in inguinal hernias. The device includes a sheet of material that has a convex side and a concave side and further embodiments with both spherical and conical sections. This device may be well suited for inguinal hernias, but the shape and stiffness of the disclosed embodiments are less than optimal for application in hernias of the intervertebral disc. Hernias tend to be broader (around the circumference of the disc) than they are high (the distance between the opposing vertebrae), a shape that does not lend itself to closure by such conical or spherical patches.

Another device involves an inflatable, barbed balloon patch used for closing inguinal hernias. This balloon is left inflated within the defect. A disadvantage of this device is that the balloon must remain inflated for the remainder of the patient's life to insure closure of the defect. Implanted, inflated devices rarely endure long periods without leaks, particularly when subjected to high loads. This is true of penile prostheses, breast implants, and artificial sphincters.

Another known method of closing inguinal hernias involves applying both heat and pressure to a planar patch and the abdominal wall surrounding the hernia. This method has the drawback of relying entirely on the integrity of the wall

surrounding the defect to hold the patch in place. The annulus is often weak in areas around a defect and may not serve as a suitable anchoring site. Further, the planar nature of the patch has all of the weaknesses discussed above.

Various devices and techniques have further been disclosed for sealing vascular puncture sites. The most relevant is a hemostatic puncture-sealing device that generally consists of an anchor, a filament and a sealing plug. The anchor is advanced into a vessel through a defect and deployed such that it resists passage back through the defect. A filament leading from the anchor and through the defect can be used to secure the anchor or aid in advancing a plug that is brought against the exterior of the defect. Such a filament, if it were to extend to the exterior of the disc, could lead to irritation of nerve roots and the formation of scar tissue in the epidural space. This is also true of any plug material that may be left either within the defect or extending to the exterior of the disc. Additionally, such devices and methods embodied for use in the vascular system require a space relatively empty of solids for the deployment of the interior anchor. This works well on the interior of a vessel, however, in the presence of the more substantial NP, the disclosed internal anchors are unlikely to orient across the defect as disclosed in their inventions.

SUMMARY OF THE INVENTION

It is an object of the disclosed invention to reduce the long-term negative consequences of back injuries such as herniated discs by repairing and/or augmenting rather than resecting the soft tissues of the disc. It is a further object of this invention to prevent or reduce the occurrence of re-herniation and disc height loss following surgical therapy for herniated discs. It is a further object of this invention to increase the AF's resistance to posterior bulging and leakage of NP material while preferably increasing its stiffness under load. It is a further object of this invention to permit the augmentation of the soft tissues of the disc in such a way so as to limit the risk of the herniation of any augmentation materials toward nerve structures posterior to the disc. It is a further object of the present invention to

shield the sensitive nerve fibers in the outer layers of the annulus from pressures within the nucleus.

In one aspect of the present invention there is provided an *in vivo* augmented functional spine unit. The augmented functional spine unit includes the two adjoining vertebrae and the intervertebral disc, composed of a central region surrounded by an annulus fibrosis and situated in the intervertebral disc space between the vertebra, and a disc herniation constraining device situated within the intervertebral disc space. The disc herniation constraining device includes an anchor fixedly coupled to an anterior portion of one of the adjoining vertebrae or annulus fibrosis and is connected to a support member by a connecting member. The support member is positioned posterior to the central region, preferably in or posterior to the annulus fibrosis. In one embodiment the central region of the functional spine unit contains a nucleus pulposus. In another embodiment of the invention, the connection member is maintained under tension between the anchor and the support member. In yet another embodiment, augmentation material is secured along at least a portion of the length of the connection member, which serves to assist the function of the intervertebral disc in supporting and separating the vertebrae, and allowing motion of one vertebra relative to the other.

In another aspect of the invention there is provided an *in vivo* augmented functional spine unit. The augmented functional spine unit includes the two adjoining vertebrae and the intervertebral disc, composed of a central region surrounded by an annulus fibrosis and situated in the intervertebral disc space between the vertebra, and a disc augmentation device situated within the intervertebral disc space. The disc augmentation device includes an anchor fixedly coupled to an anterior portion of one of the adjoining vertebrae or annulus fibrosis, augmentation material situated in the intervertebral disc space and restrained therein by a connection member secured between the anchor and the augmentation material. In an alternate embodiment, a support member is secured within the functional spine unit, the connection member extends between the anchor, the augmentation material and the support member, further restraining the movement of the augmentation

material within the central region. In yet another embodiment, the central region may contain a nucleus pulposus.

In yet another aspect of the present invention there are provided methods of augmenting a functional spine unit. These methods include using the disc herniation constraining devices and the disc augmentation devices disclosed herein.

The present invention further relates to devices and methods for sealing defects in tissue walls separating two anatomic regions of the body. Specifically, prosthetic devices and methods are disclosed which allow the closure of a defect in the AF of the human intervertebral disc, preventing the egress of material from within the disc and /or distributing pressure within the disc space across an inner wall surface of the disc.

Closure of the defect is achieved by placing a membrane or barrier on an interior aspect of the defect. In the case of the intervertebral disc, the barrier is positioned either on the interior aspect of the AF proximate to the NP or between layers of the AF. The barrier means may be inserted by dissecting a space between the annulus and nucleus. Alternatively, a portion of the nucleus and/or annulus may be resected to create adequate space.

The barrier may be inserted into position directly through the defect or alternatively it may be advanced from a remote entry through the tissue wall or other tissue neighboring the defect.

Various fixation devices can be used to secure the barrier to surrounding tissues. In the intervertebral disc, these tissues can include the surrounding AF, vertebral endplates, vertebral bodies, and even NP. Alternatively, the barrier can be held in place simply by the pressure the NP exerts on the barrier and AF where the stiffness and shape of the barrier patch may also help to maintain position and orientation within the disc. The barrier may further incorporate various self-retaining members that resist motion of the barrier within the disc. The barrier or membrane may incorporate a frame that can serve to enlarge or expand the dimensions of the barrier from a compressed state to an enlarged state. The frame can be a self expanding material such as a nickel titanium material. The barrier may further have properties that cause it to adhere to surrounding tissues either with an

adhesive, by the application of heat, or ingrowth/ongrowth of surrounding tissue. Various embodiments of the disclosed barrier are composed of either singular materials and components or a multiplicity of materials and components.

It is a further object of the present invention to reduce the limitations of current disc repair methods. It is a further object of the present invention to provide systems and methods for implanting a prosthesis along the interior aspect of the annulus through a single, small anulotomy from the posterior aspect of the disc.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing and other objects, features and advantages of the invention will be apparent from the following more particular description of preferred embodiments of the invention, as illustrated in the accompanying drawings in which like reference characters refer to the same parts throughout the different views. The drawings are not necessarily to scale, emphasis instead being placed upon illustrating the principles of the invention.

Figure 1A shows a transverse section of a portion of a functional spine unit, in which part of a vertebra and intervertebral disc are depicted.

Figure 1B shows a sagittal cross section of a portion of a functional spine unit shown in Figure 1A, in which two lumbar vertebrae and the intervertebral disc are visible.

Figure 1C shows partial disruption of the inner layers of an annulus fibrosis.

Figure 2A shows a transverse section of one aspect of the present invention prior to supporting a herniated segment.

Figure 2B shows a transverse section of the construct in Fig. 2A supporting the herniated segment.

Figure 3A shows a transverse section of another embodiment of the disclosed invention after placement of the device.

Figure 3B shows a transverse section of the construct in Fig. 3A after tension is applied to support the herniated segment.

Figure 4A shows a transverse view of an alternate embodiment of the invention.

Figure 4B shows a sagittal view of the alternate embodiment shown in Figure 4A.

Figure 5A shows a transverse view of another aspect of the present invention.

Figure 5B shows the delivery tube of Figure 5A being used to displace the herniated segment to within its pre-herniated borders.

Figure 5C shows a one-piece embodiment of the invention in an anchored and supporting position.

Figure 6 shows one embodiment of the invention supporting a weakened posterior annulus fibrosis.

Figure 7A shows a transverse section of another aspect of the disclosed invention demonstrating two stages involved in augmentation of the soft tissues of the disc.

Figure 7B shows a sagittal view of the invention shown in Figure 7A.

Figure 8 shows a transverse section of one aspect of the disclosed invention involving augmentation of the soft tissues of the disc and support/closure of the annulus fibrosis.

Figure 9A shows a transverse section of one aspect of the invention involving augmentation of the soft tissues of the disc with the flexible augmentation material anchored to the anterior lateral annulus fibrosis.

Figure 9B shows a transverse section of one aspect of the disclosed invention involving augmentation of the soft tissues of the disc with the flexible augmentation material anchored to the annulus fibrosis by a one-piece anchor.

Figure 10A shows a transverse section of one aspect of the disclosed invention involving augmentation of the soft tissues of the disc.

Figure 10B shows the construct of Figure 10A after the augmentation material has been inserted into the disc.

Figure 11 illustrates a transverse section of a barrier mounted within an annulus.

Figure 12 shows a sagittal view of the barrier of Figure 11.

Figure 13 shows a transverse section of a barrier anchored within a disc.

Figure 14 illustrates a sagittal view of the barrier shown in Figure 13.

Figure 15 illustrates the use of a second anchoring device for a barrier mounted within a disc.

Figure 16A is an transverse view of the intervertebral disc.

Figure 16B is a sagittal section along the midline of the intervertebral disc.

Figure 17 is an axial view of the intervertebral disc with the right half of a sealing means of a barrier means being placed against the interior aspect of a defect in annulus fibrosis by a dissection/delivery tool.

Figure 18 illustrates a full sealing means placed on the interior aspect of a defect in annulus fibrosis.

Figure 19 depicts the sealing means of Figure 18 being secured to tissues surrounding the defect.

Figure 20 depicts the sealing means of Figure 19 after fixation means have been passed into surrounding tissues.

Figure 21A depicts an axial view of the sealing means of Figure 20 having enlarging means inserted into the interior cavity.

Figure 21B depicts the construct of Figure 21 in a sagittal section.

Figure 22A shows an alternative fixation scheme for the sealing means and enlarging means.

Figure 22B shows the construct of Figure 22A in a sagittal section with an anchor securing a fixation region of the enlarging means to a superior vertebral body in a location proximate to the defect.

Figure 23A depicts an embodiment of the barrier means of the present invention being secured to an annulus using fixation means.

Figure 23B depicts an embodiment of the barrier means of Figure 23A secured to an annulus by two fixation darts wherein the fixation tool has been removed.

Figures 24A and 24B depict a barrier means positioned between layers of the annulus fibrosis on either side of a defect.

Figure 25 depicts an axial cross section of a large version of a barrier means.

Figure 26 depicts an axial cross section of a barrier means in position across a defect following insertion of two augmentation devices.

Figure 27 depicts the barrier means as part of an elongated augmentation device.

Figure 28A depicts an axial section of an alternate configuration of the augmentation device of Figure 27.

Figure 28B depicts a sagittal section of an alternate configuration of the augmentation device of Figure 27.

Figures 29A-D depict deployment of a barrier from an entry site remote from the defect in the annulus fibrosis.

Figures 30A, 30B, 31A, 31B, 32A, 32B, 33A, and 33B depict axial and sectional views, respectively, of various embodiments of the barrier.

Figure 34A shows a non-axisymmetric expansion means or frame.

Figures 34B and 34C illustrate perspective views of a frame mounted within an intervertebral disc.

Figures 35 and 36 illustrate alternate embodiments of the expansion means shown in Figure 34.

Figures 37A-C illustrate a front, side, and perspective view, respectively, of an alternate embodiment of the expansion means shown in Figure 34.

Figure 38 shows an alternate expansion means to that shown in Figure 37A.

Figures 39A-D illustrate a tubular expansion means having a circular cross-section.

Figures 40A-D illustrate a tubular expansion means having an oval shaped cross-section.

Figures 40E, 40F and 40I illustrate a front, back and top view, respectively of the tubular expansion means of Figure 40A having a sealing means covering an exterior surface of an annulus face.

Figures 40G and 40H show the tubular expansion means of Figure 40A having a sealing means covering an interior surface of an annulus face.

Figures 41A-D illustrate a tubular expansion means having an egg-shaped cross-section.

Figure 42A-D depicts cross sections of a preferred embodiment of sealing and enlarging means.

Figure 43A and 43B depict an alternative configuration of enlarging means.

Figure 44A and 44B depict an alternative shape of the barrier means.

Figure 45 is a section of a device used to affix sealing means to tissues surrounding a defect.

Figure 46 depicts the use of a thermal device to heat and adhere sealing means to tissues surrounding a defect.

Figure 47 depicts an expandable thermal element that can be used to adhere sealing means to tissues surrounding a defect.

Figure 48 depicts an alternative embodiment to the thermal device of Figure 46.

Figures 49A-G illustrate a method of implanting an intradiscal implant.

Figures 50A-F show an alternate method of implanting an intradiscal implant.

Figures 51A-C show another alternate method of implanting an intradiscal implant.

Figures 52A and 52B illustrate an implant guide used with the intradiscal implant system.

Figure 53A illustrates a barrier having stiffening plate elements.

Figure 53B illustrates a sectional view of the barrier of Figure 53A.

Figure 54A shows a stiffening plate.

Figure 54B shows a sectional view of the stiffening plate of Figure 54A.

Figure 55A illustrates a barrier having stiffening rod elements.

Figure 55B illustrates a sectional view of the barrier of Figure 55A.

Figure 56A illustrates a stiffening rod.

Figure 56B illustrates a sectional view of the stiffening rod of Figure 56A.

Figure 57 shows an alternate configuration for the location of the fixation devices of the barrier of Figure 44A.

Figures 58A and 58B illustrate a dissection device for an intervertebral disc.

Figures 59A and 59B illustrate an alternate dissection device for an intervertebral disc.

Figures 60A-C illustrate a dissector component.

DETAILED DESCRIPTION OF THE INVENTION

The present invention provides for an in vivo augmented functional spine unit. A functional spine unit includes the bony structures of two adjacent vertebrae (or vertebral bodies), the soft tissue (annulus fibrosis (AF), and optionally nucleus pulposus (NP)) of the intervertebral disc, and the ligaments, musculature and connective tissue connected to the vertebrae. The intervertebral disc is substantially situated in the intervertebral space formed between the adjacent vertebrae. Augmentation of the functional spine unit can include repair of a herniated disc segment, support of a weakened, torn or damaged annulus fibrosis, or the addition of material to or replacement of all or part of the nucleus pulposus. Augmentation of the functional spine unit is provided by herniation constraining devices and disc augmentation devices situated in the intervertebral disc space.

Figures 1A and 1B show the general anatomy of a functional spine unit 45. In this description and the following claims, the terms 'anterior' and 'posterior', 'superior' and 'inferior' are defined by their standard usage in anatomy, i.e., anterior is a direction toward the front (ventral) side of the body or organ, posterior is a direction toward the back (dorsal) side of the body or organ; superior is upward (toward the head) and inferior is lower (toward the feet).

Figure 1A is an axial view along the transverse axis M of a vertebral body with the intervertebral disc 15 superior to the vertebral body. Axis M shows the anterior (A) and posterior (P) orientation of the functional spine unit within the anatomy. The intervertebral disc 15 contains the annulus fibrosis (AF) 10 which surrounds a central nucleus pulposus (NP) 20. A Herniated segment 30 is depicted by a dashed-line. The herniated segment 30 protrudes beyond the pre-herniated posterior border 40 of the disc. Also shown in this figure are the left 70 and right 70' transverse spinous processes and the posterior spinous process 80.

Figure 1B is a sagittal section along sagittal axis N through the midline of two adjacent vertebral bodies 50 (superior) and 50' (inferior). Intervertebral disc space 55 is formed between the two vertebral bodies and contains intervertebral disc 15, which supports and cushions the vertebral bodies and permits movement of the two vertebral bodies with respect to each other and other adjacent functional spine units.

Intervertebral disc 15 is comprised of the outer AF 10 which normally surrounds and constrains the NP 20 to be wholly within the borders of the intervertebral disc space. In Figs. 1A and 1B, herniated segment 30, represented by the dashed-line, has migrated posterior to the pre-herniated border 40 of the posterior AF of the disc. Axis M extends between the anterior (A) and posterior (P) of the functional spine unit. The vertebral bodies also include facet joints 60 and the superior 90 and inferior 90' pedicle that form the neural foramen 100. Disc height loss occurs when the superior vertebral body 50 moves inferiorly relative to the inferior vertebral body 50'.

Partial disruption 121 of the inner layers of the annulus 10 without a true perforation has also been linked to chronic low back pain. Such a disruption 4 is illustrated in Figure 1C. It is thought that weakness of these inner layers forces the sensitive outer annular lamellae to endure higher stresses. This increased stress stimulates the small nerve fibers penetrating the outer annulus, which results in both localized and referred pain.

In one embodiment of the present invention, the disc herniation constraining devices 13 provide support for returning all or part of the herniated segment 30 to a position substantially within its pre-herniated borders 40. The disc herniation constraining device includes an anchor which is positioned at a site within the functional spine unit, such as the superior or inferior vertebral body, or the anterior medial, or anterior lateral annulus fibrosis. The anchor is used as a point against which all or part of the herniated segment is tensioned so as to return the herniated segment to its pre-herniated borders, and thereby relieve pressure on otherwise compressed neural tissue and structures. A support member is positioned in or posterior to the herniated segment, and is connected to the anchor by a connecting

member. Sufficient tension is applied to the connecting member so that the support member returns the herniated segment to a pre-herniated position. In various embodiments, augmentation material is secured within the intervertebral disc space, which assists the NP in cushioning and supporting the inferior and superior vertebral bodies. An anchor secured in a portion of the functional spine unit and attached to the connection member and augmentation material limits movement of the augmentation material within the intervertebral disc space. A supporting member, located opposite the anchor, may optionally provide a second point of attachment for the connection member and further hinder the movement of the augmentation material within the intervertebral disc space.

Figures 2A and 2B depict one embodiment of device 13. Figure 2A shows the elements of the constraining device in position to correct the herniated segment. Anchor 1 is securely established in a location within the functional spine unit, such as the anterior AF shown in the figure. Support member 2 is positioned in or posterior to herniated segment 30. Leading from and connected to anchor 1 is connection member 3, which serves to connect anchor 1 to support member 2. Depending on the location chosen for support member 2, the connection member may traverse through all or part of the herniated segment.

Figure 2B shows the positions of the various elements of the herniation constraining device 13 when the device 13 is supporting the herniated segment. Tightening connection member 2 allows it to transmit tensile forces along its length, which causes herniated segment 30 to move anteriorly, i.e., in the direction of its pre-herniated borders. Once herniated segment 30 is in the desired position, connection member 3 is secured in a permanent fashion between anchor 1 and support member 2. This maintains tension between anchor 1 and support member 2 and restricts motion of the herniated segment to within the pre-herniated borders 40 of the disc. Support member 2 is used to anchor to herniated segment 30, support a weakened AF in which no visual evidence of herniation is apparent, and may also be used to close a defect in the AF in the vicinity of herniated segment 30.

Anchor 1 is depicted in a representative form, as it can take one of many suitable shapes, be made from one of a variety of biocompatible materials, and be

constructed so as to fall within a range of stiffness. It can be a permanent device constructed of durable plastic or metal or can be made from a resorbable material such as polylactic acid (PLA) or polyglycolic acid (PGA). Specific embodiments are not shown, but many possible designs would be obvious to anyone skilled in the art. Embodiments include, but are not limited to, a barbed anchor made of PLA or a metal coil that can be screwed into the anterior AF. Anchor 1 can be securely established within a portion of the functional spine unit in the usual and customary manner for such devices and locations, such as being screwed into bone, sutured into tissue or bone, or affixed to tissue or bone using an adhesive method, such as cement, or other suitable surgical adhesives. Once established within the bone or tissue, anchor 1 should remain relatively stationary within the bone or tissue.

Support member 2 is also depicted in a representative format and shares the same flexibility in material and design as anchor 1. Both device elements can be of the same design, or they can be of different designs, each better suited to being established in healthy and diseased tissue respectively. Alternatively, in other forms, support member 2 can be a cap or a bead shape, which also serves to secure a tear or puncture in the AF, or it can be bar or plate shaped, with or without barbs to maintain secure contact with the herniated segment. Support member 2 can be established securely to, within, or posterior to the herniated segment.

The anchor and support member can include suture, bone anchors, soft tissue anchors, tissue adhesives, and materials that support tissue ingrowth although other forms and materials are possible. They may be permanent devices or resorbable. Their attachment to a portion of FSU and herniated segment must be strong enough to resist the tensional forces that result from repair of the hernia and the loads generated during daily activities.

Connection member 3 is also depicted in representative fashion. Member 3 may be in the format of a flexible filament, such as a single or multi-strand suture, wire, or perhaps a rigid rod or broad band of material, for example. The connection member can further include suture, wire, pins, and woven tubes or webs of material. It can be constructed from a variety of materials, either permanent or resorbable, and can be of any shape suitable to fit within the confines of the intervertebral disc

space. The material chosen is preferably adapted to be relatively stiff while in tension, and relatively flexible against all other loads. This allows for maximal mobility of the herniated segment relative to the anchor without the risk of the supported segment moving outside of the pre-herniated borders of the disc. The connection member may be an integral component of either the anchor or support member or a separate component. For example, the connection member and support member could be a length of non-resorbing suture that is coupled to an anchor, tensioned against the anchor, and sewn to the herniated segment.

Figures 3A and 3B depict another embodiment of device 13. In Figure 3A the elements of the herniation constraining device are shown in position prior to securing a herniated segment. Anchor 1 is positioned in the AF and connection member 3 is attached to anchor 1. Support member 4 is positioned posterior to the posterior-most aspect of herniated segment 30. In this way, support member 4 does not need to be secured in herniated segment 30 to cause herniated segment 30 to move within the pre-herniated borders 40 of the disc. Support member 4 has the same flexibility in design and material as anchor 1, and may further take the form of a flexible patch or rigid plate or bar of material that is either affixed to the posterior aspect of herniated segment 30 or is simply in a form that is larger than any hole in the AF directly anterior to support member 4. Figure 3B shows the positions of the elements of the device when tension is applied between anchor 1 and support member 4 along connection member 3. The herniated segment is displaced anteriorly, within the pre-herniated borders 40 of the disc.

Figures 4A and 4B show five examples of suitable anchoring sites within the FSU for anchor 1. Figure 4A shows an axial view of anchor 1 in various positions within the anterior and lateral AF. Figure 4B similarly shows a sagittal view of the various acceptable anchoring sites for anchor 1. Anchor 1 is secured in the superior vertebral body 50, inferior vertebral body 50' or anterior AF 10, although any site that can withstand the tension between anchor 1 and support member 2 along connection member 3 to support a herniated segment within its pre-herniated borders 40 is acceptable.

Generally, a suitable position for affixing one or more anchors is a location anterior to the herniated segment such that, when tension is applied along connection member 3, herniated segment 30 is returned to a site within the pre-herniated borders 40. The site chosen for the anchor should be able to withstand the tensile forces applied to the anchor when the connection member is brought under tension. Because most symptomatic herniations occur in the posterior or posterior lateral directions, the preferable site for anchor placement is anterior to the site of the herniation. Any portion of the involved FSU is generally acceptable, however the anterior, anterior medial, or anterior lateral AF is preferable. These portions of the AF have been shown to have considerably greater strength and stiffness than the posterior or posterior lateral portions of the AF. As shown in Figures 4A and 4B, anchor 1 can be a single anchor in any of the shown locations, or there can be multiple anchors 1 affixed in various locations and connected to a support member 2 to support the herniated segment. Connection member 3 can be one continuous length that is threaded through the sited anchors and the support member, or it can be several individual strands of material each terminated under tension between one or more anchors and one or more support members.

In various forms of the invention, the anchor(s) and connection member(s) may be introduced and implanted in the patient, with the connection member under tension. Alternatively, those elements may be installed, without introducing tension to the connection member, but where the connection member is adapted to be under tension when the patient is in a non-horizontal position, i.e., resulting from loading in the intervertebral disc.

Figures 5A-C show an alternate embodiment of herniation constraining device 13A. In this series of figures, device 13A, a substantially one-piece construct, is delivered through a delivery tube 6, although device 13A could be delivered in a variety of ways including, but not limited to, by hand or by a hand held grasping instrument. In Figure 5A, device 13A in delivery tube 6 is positioned against herniated segment 30. In Figure 5B, the herniated segment is displaced within its pre-herniated borders 40 by device 13A and/or delivery tube 6 such that when, in Figure 5C, device 13A has been delivered through delivery tube 6, and

secured within a portion of the FSU, the device supports the displaced herniated segment within its pre-herniated border 40. Herniation constraining device 13A can be made of a variety of materials and have one of many possible forms so long as it allows support of the herniated segment 30 within the pre-herniated borders 40 of the disc. Device 13A can anchor the herniated segment 30 to any suitable anchoring site within the FSU, including, but not limited to the superior vertebral body, inferior vertebral body, or anterior AF. Device 13A may be used additionally to close a defect in the AF of herniated segment 30. Alternatively, any such defect may be left open or may be closed using another means.

Figures 6 depicts the substantially one-piece device 13A supporting a weakened segment 30' of the posterior AF 10'. Device 13A is positioned in or posterior to the weakened segment 30' and secured to a portion of the FSU, such as the superior vertebral body 50, shown in the figure, or the inferior vertebral body 50' or anterior or anterior-lateral annulus fibrosis 10. In certain patients, there may be no obvious herniation found at surgery. However, a weakened or torn AF that may not be protruding beyond the pre-herniated borders of the disc may still induce the surgeon to remove all or part of the NP in order to decrease the risk of herniation. As an alternative to discectomy, any of the embodiments of the invention may be used to support and perhaps close defects in weakened segments of AF.

A further embodiment of the present invention involves augmentation of the soft tissues of the intervertebral disc to avoid or reverse disc height loss. Figures 7A and 7B show one embodiment of device 13 securing augmentation material in the intervertebral disc space 55. In the left side of Figure 7A, anchors 1 have been established in the anterior AF 10. Augmentation material 7 is in the process of being inserted into the disc space along connection member 3 which, in this embodiment, has passageway 9. Support member 2' is shown ready to be attached to connection member 3 once the augmentation material 7 is properly situated. In this embodiment, connection member 3 passes through an aperture 11 in support member 2', although many other methods of affixing support member 2' to connection member 3 are possible and within the scope of this invention.

Augmentation material 7 may have a passageway 9, such as a channel, slit or the like, which allows it to slide along the connection member 3, or augmentation material 7 may be solid, and connection member 3 can be threaded through augmentation material by means such as needle or other puncturing device. Connection member 3 is affixed at one end to anchor 1 and terminated at its other end by a support member 2', one embodiment of which is shown in the figure in a cap-like configuration. Support member 2' can be affixed to connection member 3 in a variety of ways, including, but not limited to, swaging support member 2' to connection member 3. In a preferred embodiment, support member 2' is in a cap configuration and has a dimension (diameter or length and width) larger than the optional passageway 9, which serves to prevent augmentation material 7 from displacing posteriorly with respect to anchor 1. The right half of the intervertebral disc of Figure 7A (axial view) and Figure 7B (sagittal view) show augmentation material 7 that has been implanted into the disc space 55 along connection member 3 where it supports the vertebral bodies 50 and 50'. Figure 7A shows an embodiment in which support member 2' is affixed to connection member 3 and serves only to prevent augmentation material 7 from moving off connection member 3. The augmentation device is free to move within the disc space. Figure 7B shows an alternate embodiment in which support member 2' is embedded in a site in the functional spine unit, such as a herniated segment or posterior annulus fibrosis, to further restrict the movement of augmentation material 7 or spacer material within the disc space.

Augmentation or spacer material can be made of any biocompatible, preferably flexible, material. Such a flexible material is preferably fibrous, like cellulose or bovine or autologous collagen. The augmentation material can be plug or disc shaped. It can further be cube-like, ellipsoid, spheroid or any other suitable shape. The augmentation material can be secured within the intervertebral space by a variety of methods, such as but not limited to, a suture loop attached to, around, or through the material, which is then passed to the anchor and support member.

Figures 8, 9A, 9B and 10A and 10B depict further embodiments of the disc herniation constraining device 13B in use for augmenting soft tissue, particularly

tissue within the intervertebral space. In the embodiments shown in Figures 8 and 9A, device 13B is secured within the intervertebral disc space providing additional support for NP 20. Anchor 1 is securely affixed in a portion of the FSU, (anterior AF 10 in these figures). Connection member 3 terminates at support member 2, preventing augmentation material 7 from migrating generally posteriorly with respect to anchor 1. Support member 2 is depicted in these figures as established in various locations, such as the posterior AF 10' in Figure 8, but support member 2 may be anchored in any suitable location within the FSU, as described previously. Support member 2 may be used to close a defect in the posterior AF. It may also be used to displace a herniated segment to within the pre-herniated borders of the disc by applying tension between anchoring means 1 and 2 along connection member 3.

Figure 9A depicts anchor 1, connection member 3, spacer material 7 and support member 2' (shown in the "cap"-type configuration) inserted as a single construct and anchored to a site within the disc space, such as the inferior or superior vertebral bodies. This configuration simplifies insertion of the embodiments depicted in Figures 7 and 8 by reducing the number of steps to achieve implantation. Connection member 3 is preferably relatively stiff in tension, but flexible against all other loads. Support member 2' is depicted as a bar element that is larger than passageway 9 in at least one plane.

Figure 9B depicts a variation on the embodiment depicted in Figure 9A. Figure 9B shows substantially one-piece disc augmentation device 13C, secured in the intervertebral disc space. Device 13C has anchor 1, connection member 3 and augmentation material 7. Augmentation material 7 and anchor 1 could be pre-assembled prior to insertion into the disc space 55 as a single construct. Alternatively, augmentation material 7 could be inserted first into the disc space and then anchored to a portion of the FSU by anchor 1.

Figures 10A and 10B show yet another embodiment of the disclosed invention, 13D. In Figure 10A, two connection members 3 and 3' are attached to anchor 1. Two plugs of augmentation material 7 and 7' are inserted into the disc space along connection members 3 and 3'. Connection members 3 and 3' are then bound together (e.g., knotted together, fused, or the like). This forms loop 3" that

serves to prevent augmentation materials 7 and 7' from displacing posteriorly. Figure 10B shows the position of the augmentation material 7 after it is secured by the loop 3" and anchor 1. Various combinations of augmentation material, connecting members and anchors can be used in this embodiment, such as using a single plug of augmentation material, or two connection members leading from anchor 1 with each of the connection members being bound to at least one other connection member. It could further be accomplished with more than one anchor with at least one connection member leading from each anchor, and each of the connection members being bound to at least one other connection member.

Any of the devices described herein can be used for closing defects in the AF whether created surgically or during the herniation event. Such methods may also involve the addition of biocompatible material to either the AF or NP. This material could include sequestered or extruded segments of the NP found outside the pre-herniated borders of the disc.

Figures 11-15 illustrate devices used in and methods for closing a defect in an annulus fibrosis. One method involves the insertion of a barrier or barrier means 12 into the disc 15. This procedure can accompany surgical discectomy. It can also be done without the removal of any portion of the disc 15 and further in combination with the insertion of an augmentation material or device into the disc 15.

The method consists of inserting the barrier 12 into the interior of the disc 15 and positioning it proximate to the interior aspect of the annular defect 16. The barrier material is preferably considerably larger in area than the size of the defect 16, such that at least some portion of the barrier means 12 abuts healthier annulus fibrosis 10. The device acts to seal the annular defect 16, recreating the closed isobaric environment of a healthy disc nucleus 20. This closure can be achieved simply by an over-sizing of the implant relative to the defect 16. It can also be achieved by affixing the barrier means 12 to tissues within the functional spinal unit. In a preferred aspect of the present invention, the barrier 12 is affixed to the annulus surrounding the annular defect 16. This can be achieved with sutures, staples, glues or other suitable fixation means or fixation device 14. The barrier means 12 can also

be larger in area than the defect 16 and be affixed to a tissue or structure opposite the defect 16, i.e. anterior tissue in the case of a posterior defect.

The barrier means 12 is preferably flexible in nature. It can be constructed of a woven material such as Dacron™ or Nylon™, a synthetic polymaide or polyester, a polyethplene, and can further be an expanded material, such as expanded polytetrafluroethelene (e-PTFE), for example. The barrier means 12 can also be a biologic material such as cross-linked collagen or cellulous.

The barrier means 12 can be a single piece of material. It can have an expandable means or component that allows it to be expanded from a compressed state after insertion into the interior of the disc 15. This expandable means can be active, such as a balloon, or passive, such as a hydrophilic material. The expandable means can also be a self-expanding elastically deforming material, for example.

Figures 11 and 12 illustrate a barrier 12 mounted within an annulus 10 and covering an annular defect 16. The barrier 12 can be secured to the annulus 10 with a fixation mechanism or fixation means14. The fixation means 14 can include a plurality of suture loops placed through the barrier 12 and the annulus 10. Such fixation can prevent motion or slipping of the barrier 12 away from the annular defect 16.

The barrier means 12 can also be anchored to the disc 15 in multiple locations. In one preferred embodiment, shown in Figures 13 and 14, the barrier means 12 can be affixed to the annulus tissue 10 in or surrounding the defect and further affixed to a secondary fixation site opposite the defect, e.g. the anterior annulus 10 in a posterior herniation, or the inferior 50' or superior 50 vertebral body. For example, fixation means 14 can be used to attach the barrier 12 to the annulus 10 near the defect 16, while an anchoring mechanism 18 can secure the barrier 12 to a secondary fixation site. A connector 22 can attach the barrier 12 to the anchor 18. Tension can be applied between the primary and secondary fixation sites through a connector 22 so as to move the annular defect 16 toward the secondary fixation site. This may be particularly beneficial in closing defects 16 that result in posterior herniations. By using this technique, the herniation can be moved and supported

away from any posterior neural structures while further closing any defect in the annulus 10.

The barrier means 12 can further be integral to a fixation means such that the barrier means affixes itself to tissues within the functional spinal unit.

Any of the methods described above can be augmented by the use of a second barrier or a second barrier means 24 placed proximate to the outer aspect of the defect 16 as shown in Figure 15. The second barrier 24 can further be affixed to the inner barrier means 12 by the use of a fixation means 14 such as suture material.

Figures 16A and 16B depict intervertebral disc 15 comprising nucleus pulposus 20 and annulus fibrosis 10. Nucleus pulposus 20 forms a first anatomic region and extra-discal space 500 (any space exterior to the disc) forms a second anatomic region wherein these regions are separated by annulus fibrosis 10.

Figure 16A is an axial (transverse) view of the intervertebral disc. A posterior lateral defect 16 in annulus fibrosis10 has allowed a segment 30 of nucleus pulposus 20 to herniate into an extra discal space 500. Interior aspect 32 and exterior aspect 34 are shown, as are the right 70' and left 70 transverse processes and posterior process 80.

Figure 16B is a sagittal section along the midline intervertebral disc. Superior pedicle 90 and inferior pedicle 90' extend posteriorly from superior vertebral body 95 and inferior vertebral body 95' respectively.

To prevent further herniation of the nucleus 20 and to repair any present herniation, in a preferred embodiment, a barrier or barrier means 12 can be placed into a space between the annulus 10 and the nucleus 20 proximate to the inner aspect 32 of defect 16, as depicted in Figures 17 and 18. The space can be created by blunt dissection. Dissection can be achieved with a separate dissection instrument, with the barrier means 12 itself, or a combined dissection/barrier delivery tool 100. This space is preferably no larger than the barrier means such that the barrier means 12 can be in contact with both annulus 10 and nucleus 20. This allows the barrier means 12 to transfer load from the nucleus 20 to the annulus 10 when the disc is pressurized during activity.

In position, the barrier means 12 preferably spans the defect 16 and extends along the interior aspect 36 of the annulus 10 until it contacts healthy tissues on all sides of the defect 16. Depending on the extent of the defect 16, the contacted tissues can include the annulus 10, cartilage overlying the vertebral endplates, and/or the endplates themselves.

In the preferred embodiment, the barrier means 12 consists of two components – a sealing means or sealing component 51 and an enlarging means or enlarging component 53, shown in Figures 21A and 21B.

The sealing means 51 forms the periphery of the barrier 12 and has an interior cavity 17. There is at least one opening 8 leading into cavity 17 from the exterior of the sealing means 51. Sealing means 51 is preferably compressible or collapsible to a dimension that can readily be inserted into the disc 15 through a relatively small hole. This hole can be the defect 16 itself or a site remote from the defect 16. The sealing means 51 is constructed from a material and is formed in such a manner as to resist the passage of fluids and other materials around sealing means 51 and through the defect 16. The sealing means 51 can be constructed from one or any number of a variety of materials including, but not limited to PTFE, e-PTFE, Nylon™, Marlex ™, high-density polyethylene, and/or collagen. The thickness of the sealing component has been found to be optimal between 0.001 inches (0.127mm) and 0.063 inches (1.600mm).

The enlarging means 53 can be sized to fit within cavity 17 of sealing means 51. It is preferably a single object of a dimension that can be inserted through the same defect 16 through which the sealing means 51 was passed. The enlarging means 53 can expand the sealing means 51 to an expanded state as it is passed into cavity 17. One purpose of enlarging means 53 is to expand sealing means 51 to a size greater than that of the defect 16 such that the assembled barrier 12 prevents passage of material through the defect 16. The enlarger 53 can further impart stiffness to the barrier 12 such that the barrier 12 resists the pressures within nucleus pulposus 20 and expulsion through the defect 16. The enlarging means 53 can be constructed from one or any number of materials including, but not limited to, silicon rubber, various plastics, stainless steel, nickel titanium alloys, or other

metals. These materials may form a solid object, a hollow object, coiled springs or other suitable forms capable of filling cavity 17 within sealing means 51.

The sealing means 51, enlarging means 53, or the barrier means 12 constructs can further be affixed to tissues either surrounding the defect 16 or remote from the defect 16. In the preferred embodiment, no aspect of a fixation means or fixation device or the barrier means 12 nor its components extend posterior to the disc 15 or into the extradiscal region 500, avoiding the risk of contacting and irritating the sensitive nerve tissues posterior to the disc 15.

In a preferred embodiment, the sealing means 51 is inserted into the disc 15 proximate the interior aspect 36 of the defect. The sealing means 51 is then affixed to the tissues surrounding the defect using a suitable fixation means, such as suture or a soft-tissue anchor. The fixation procedure is preferably performed from the interior of the sealing means cavity 17 as depicted in Figures 19 and 20. A fixation delivery instrument 110 is delivered into cavity 17 through opening 8 in the sealing means 51. Fixation devices 14 can then be deployed through a wall of the sealing means 53 into surrounding tissues. Once the fixation means 14 have been passed into surrounding tissue, the fixation delivery instrument 110 can be removed from the disc 15. This method eliminates the need for a separate entryway into the disc 15 for delivery of fixation means 14. It further minimizes the risk of material leaking through sealing means 51 proximate to the fixation means 14. One or more fixation means 14 can be delivered into one or any number of surrounding tissues including the superior 95 and inferior 95' vertebral bodies. Following fixation of the sealing means 51, the enlarging means 53 can be inserted into cavity 17 of the sealing means 51 to further expand the barrier means 12 construct as well as increase its stiffness, as depicted in Figures 21A and 21B. The opening 8 into the sealing means 51 can then be closed by a suture or other means, although this is not a requirement of the present invention. In certain cases, insertion of a separate enlarging means may not be necessary if adequate fixation of the sealing means 51 is achieved.

Another method of securing the barrier 12 to tissues is to affix the enlarging means 53 to tissues either surrounding or remote from the defect 16. The enlarging means 53 can have an integral fixation region 4 that facilitates securing it to tissues

as depicted in Figures 22A, 22B, 32A and 43B. This fixation region 4 can extend exterior to sealing means 51 either through opening 8 or through a separate opening. Fixation region 4 can have a hole through which a fixation means or fixation device 14 can be passed. In a preferred embodiment, the barrier 12 is affixed to at least one of the surrounding vertebral bodies (95 and 95') proximate to the defect using a bone anchor 14'. The bone anchor 14' can be deployed into the vertebral bodies 50, 50' at some angle between 0° and 180° relative to a bone anchor deployment tool. As shown the bone anchor 14' is mounted at 90° relative to the bone anchor deployment tool. Alternatively, the enlarging means 53 itself can have an integral fixation device 14 located at a site or sites along its length.

Another method of securing the barrier means 12 is to insert the barrier means 12 through the defect 16 or another opening into the disc 15, position it proximate to the interior aspect 36 of the defect 16, and pass at least one fixation means 14 through the annulus 10 and into the barrier 12. In a preferred embodiment of this method, the fixation means 14 can be darts 15 and are first passed partially into annulus 10 within a fixation device 120, such as a hollow needle. As depicted in Figures 23A and 23B, fixation means 25 can be advanced into the barrier means 12 and fixation device 120 removed. Fixation means 25 preferably have two ends, each with a means to prevent movement of that end of the fixation device. Using this method, the fixation means can be lodged in both the barrier 12 and annulus fibrosis 10 without any aspect of fixation means 25 exterior to the disc in the extradiscal region 500.

In another aspect of the present invention, the barrier (or "patch") 12 can be placed between two neighboring layers 33,37 (lamellae) of the annulus 10 on either or both sides of the defect 16 as depicted in Figures 24A and 24B. Figure 24A shows an axial view while 24B shows a sagittal cross section. Such positioning spans the defect 16. The barrier means 12 can be secured using the methods outlined.

A dissecting tool can be used to form an opening extending circumferentially31 within the annulus fibrosus such that the barrier can be inserted into the opening. Alternatively, the barrier itself can have a dissecting edge such

that it can be driven at least partially into the sidewalls of defect or opening 16 in the annulus. This process can make use of the naturally layered structure in the annulus in which adjacent layers 33, 37 are defined by a circumferentially extending boundary 35 between the layers.

Another embodiment of the barrier 12 is a patch having a length, oriented along the circumference of the disc, which is substantially greater than its height, which is oriented along the distance separating the surrounding vertebral bodies. A barrier 12 having a length greater than its height is illustrated in Figure 25. The barrier 12 can be positioned across the defect 16 as well as the entirety of the posterior aspect of the annulus fibrosis 10. Such dimensions of the barrier 12 can help to prevent the barrier 12 from slipping after insertion and can aid in distributing the pressure of the nucleus 20 evenly along the posterior aspect of the annulus 10.

The barrier 12 can be used in conjunction with an augmentation device 11 inserted within the annulus 10. The augmentation device 11 can include separate augmentation devices 42 as shown in Figure 26. The augmentation device 11 can also be a single augmentation device 44 and can form part of the barrier 12 as barrier region 300, coiled within the annulus fibrosis 10, as shown in Figure 27. Either the barrier 12 or barrier region 300 can be secured to the tissues surrounding the defect 16 by fixation devices or darts 25, or be left unconstrained

In another embodiment of the present invention, the barrier or patch 12 may be used as part of a method to augment the intervertebral disc. In one aspect of this method, augmentation material or devices are inserted into the disc through a defect (either naturally occurring or surgically generated). Many suitable augmentation materials and devices are discussed above and in the prior art. As depicted in Figure 26, the barrier means is then inserted to aid in closing the defect and/or to aid in transferring load from the augmentation materials/devices to healthy tissues surrounding the defect. In another aspect of this method, the barrier means is an integral component to an augmentation device. As shown in Figures 27, 28A and 28B, the augmentation portion may comprise a length of elastic material that can be inserted linearly through a defect in the annulus. A region 300 of the length forms the barrier means of the present invention and can be positioned proximate to the

interior aspect of the defect once the nuclear space is adequately filled. Barrier region 300 may then be affixed to surrounding tissues such as the AF and/or the neighboring vertebral bodies using any of the methods and devices described above.

Figures 28A and 28B illustrate axial and sagittal sections, respectively, of an alternate configuration of an augmentation device 38. In this embodiment, barrier region 300 extends across the defect 16 and has fixation region 4 facilitating fixation of the device 13 to superior vertebral body 50 with anchor 14'.

Figures 29A-D illustrate the deployment of a barrier 12 from an entry site 800 remote from the defect in the annulus fibrosis 10. Figure 29A shows insertion instrument 130 with a distal end positioned within the disc space occupied by nucleus pulposus 20. Figure 29B depicts delivery catheter 140 exiting the distal end of insertion instrument 130 with barrier 12 on its distal end. Barrier 12 is positioned across the interior aspect of the defect 16. Figure 29C depicts the use of an expandable barrier 12' wherein delivery catheter 140 is used to expand the barrier 12' with balloon 150 on its distal end. Balloon 150 may exploit heat to further adhere barrier 12' to surrounding tissue. Figure 29D depicts removal of balloon 150 and delivery catheter 140 from the disc space leaving expanded barrier means 12' positioned across defect 16.

Another method of securing the barrier means 12 is to adhere it to surrounding tissues through the application of heat. In this embodiment, the barrier means 12 includes a sealing means 51 comprised of a thermally adherent material that adheres to surrounding tissues upon the application of heat. The thermally adherent material can include thermoplastic, collagen, or a similar material. The sealing means 51 can further comprise a separate structural material that adds strength to the thermally adherent material, such as a woven Nylon™ or Marlex™. This thermally adherent sealing means preferably has an interior cavity 17 and at least one opening 8 leading from the exterior of the barrier means into cavity 17. A thermal device can be attached to the insertion instrument shown in Figures 29C and 29D. The insertion instrument 130 having a thermal device can be inserted into cavity 17 and used to heat sealing means 51 and surrounding tissues. This device can be a simple thermal element, such as a resistive heating coil, rod or wire. It can

further be a number of electrodes capable of heating the barrier means and surrounding tissue through the application of radio frequency (RF) energy. The thermal device can further be a balloon 150, 150', as shown in Figure 47, capable of both heating and expanding the barrier means. Balloon 150, 150' can either be inflated with a heated fluid or have electrodes located about its surface to heat the barrier means with RF energy. Balloon 150, 150' is deflated and removed after heating the sealing means. These thermal methods and devices achieve the goal of adhering the sealing means to the AF and NP and potentially other surrounding tissues. The application of heat can further aid the procedure by killing small nerves within the AF, by causing the defect to shrink, or by causing cross-linking and/or shrinking of surrounding tissues. An expander or enlarging means 53 can also be an integral component of barrier 12 inserted within sealing means 51. After the application of heat, a separate enlarging means 53 can be inserted into the interior cavity of the barrier means to either enlarge the barrier 12 or add stiffness to its structure. Such an enlarging means is preferably similar in make-up and design to those described above. Use of an enlarging means may not be necessary in some cases and is not a required component of this method.

The barrier means 12 shown in Figure 25 preferably has a primary curvature or gentle curve along the length of the patch or barrier 12 that allows it to conform to the inner circumference of the AF 10. This curvature may have a single radius R as shown in Figures 44A and 44B or may have multiple curvatures. The curvature can be fabricated into the barrier 12 and/or any of its components. For example, the sealing means can be made without an inherent curvature while the enlarging means can have a primary curvature along its length. Once the enlarging means is placed within the sealing means the overall barrier means assembly takes on the primary curvature of the enlarging means. This modularity allows enlarging means with specific curvatures to be fabricated for defects occurring in various regions of the annulus fibrosis.

The cross section of the barrier 12 can be any of a number of shapes. Each embodiment exploits a sealing means 51 and an enlarging means 53 that may further add stiffness to the overall barrier construct. Figures 30A and 30B show an

elongated cylindrical embodiment with enlarging means 53 located about the long axis of the device. Figures 31A and 31B depict a barrier means comprising an enlarging means 53 with a central cavity 49. Figures 32A and 32B depict a barrier means comprising a non-axisymmetric sealing means 51. In use, the longer section of sealing means 51 as seen on the left side of this figure would extend between opposing vertebra 50 and 50'. Figures 33A and 33B depict a barrier means comprising a non-axisymmetric sealing means 51 and enlarger 53. The concave portion of the barrier means preferably faces nucleus pulposus 20 while the convex surface faces the defect 16 and the inner aspect of the annulus fibrosis 10. This embodiment exploits pressure within the disc to compress sealing means 51 against neighboring vertebral bodies 50 and 50' to aid in sealing. The 'C' shape as shown in Figure 33A is the preferred shape of the barrier wherein the convex portion of the patch rests against the interior aspect of the AF while the concave portion faces the NP. To improve the sealing ability of such a patch, the upper and lower portions of this 'C' shaped barrier means are positioned against the vertebral endplates or overlying cartilage. As the pressure within the nucleus increases, these portions of the patch are pressurized toward the endplates with an equivalent pressure, preventing the passage of materials around the barrier means. Dissecting a matching cavity prior to or during patch placement can facilitate use of such a 'C' shaped patch.

Figures 34 through 41 depict various enlarging or expansion devices 53 that can be employed to aid in expanding a sealing element 51 within the intervertebral disc 15. Each embodiment can be covered by, coated with, or cover the sealing element 51. The sealing means 51 can further be woven through the expansion means 53. The sealing element 51 or membrane can be a sealer which can prevent flow of a material from within the annulus fibrosis of the intervertebral disc through a defect in the annulus fibrosis. The material within the annulus can include nucleus pulposus or a prosthetic augmentation device, such as a hydrogel.

Figures 34 through 38 depict alternative patterns to that illustrated in Figure 33A. Figure 33A shows the expansion devices 53 within the sealing means 51. The sealing means can alternatively be secured to one or another face (concave or

convex) of the expansion means 53. This can have advantages in reducing the overall volume of the barrier means 12, simplifying insertion through a narrow cannula. It can also allow the barrier means 12 to induce ingrowth of tissue on one face and not the other. The sealing means 51 can be formed from a material that resists ingrowth such as expanded polytetraflouroethylene (e-PTFE). The expansion means 53 can be constructed of a metal or polymer that encourages ingrowth. If the e-PTFE sealing means 51 is secured to the concave face of the expansion means 53, tissue can grow into the expansion means 53 from outside of the disc 15, helping to secure the barrier means 12 in place and seal against egress of materials from within the disc 15.

The expansion means 53 shown in Figure 33A can be inserted into the sealing means 51 once the sealing means 51 is within the disc 15. Alternatively, the expansion means 53 and sealing means 51 can be integral components of the barrier means 12 that can be inserted as a unit into the disc.

The patterns shown in Figures 34 through 38 can preferably be formed from a relatively thin sheet of material. The material may be a polymer, metal, or gel, however, the superelastic properties of nickel titanium alloy (NITINOL) makes this metal particularly advantageous in this application. Sheet thickness can generally be in a range of 0.1 mm to 0.6 mm and for certain embodiments has been found to be optimal if between 0.003" to 0.015"(0.0762mm to 0.381mm), for the thickness to provide adequate expansion force to maintain contact between the sealing means 51 and surrounding vertebral endplates. The pattern may be Wire Electro-Discharge Machined, cut by laser, chemically etched, or formed by other suitable means.

Figure 34A shows an embodiment of a non-axisymmetric expander 153 having a superior edge 166 and an inferior edge 168. The expander 153 can form a frame of barrier 12. This embodiment comprises dissecting surfaces or ends 160, radial elements or fingers 162 and a central strut 164. The circular shape of the dissecting ends 160 aids in dissecting through the nucleus pulposus 20 and/or along or between an inner surface of the annulus fibrosis 10. The distance between the left-most and right-most points on the dissecting ends is the expansion means length 170. This length 170 preferably lies along the inner perimeter of the posterior

annulus following implantation. The expander length 170 can be as short as 3mm and as long as the entire interior perimeter of the annulus fibrosis. The superior-inferior height of these dissecting ends 160 is preferably similar to or larger than the posterior disc height.

This embodiment employs a multitude of fingers 162 to aid in holding a flexible sealer or membrane against the superior and inferior vertebral endplates. The distance between the superior-most point of the superior finger and the inferior-most point on the inferior finger is the expansion means height 172. This height 172 is preferably greater than the disc height at the inner surface of the posterior annulus. The greater height 172 of the expander 153 allows the fingers 162 to deflect along the superior and inferior vertebral endplates, enhancing the seal of the barrier means 12 against egress of material from within the disc 15.

The spacing between the fingers 162 along the expander length 170 can be tailored to provide a desired stiffness of the expansion means 153. Greater spacing between any two neighboring fingers 162 can further be employed to insure that the fingers 170 do not touch if the expansion means 153 is required to take a bend along its length. The central strut 164 can connect the fingers and dissecting ends and preferably lies along the inner surface of the annulus 10 when seated within the disc 15. Various embodiments may employ struts 164 of greater or lesser heights and thicknesses to vary the stiffness of the overall expansion means 153 along its length 170 and height 172.

Figure 35 depicts an alternative embodiment to the expander 153 of Figure 34. Openings or slots 174 can be included along the central strut 164. These slots 174 promote bending of the expander 153 and fingers 162 along a central line 176 connecting the centers of the dissecting ends 160. Such central flexibility has been found to aid against superior or inferior migration of the barrier means or barrier 12 when the barrier 12 has not been secured to surrounding tissues.

Figures 34B and 34C depict different perspective views of a preferred embodiment of the expander/frame 153 within an intervertebral disc 15. Expander 53 is in its expanded condition and lies along and/or within the posterior wall 21 and extends around the lateral walls 23 of the annulus fibrosis 10. The superior 166 and

inferior 168 facing fingers 162 of expander 153 extend along the vertebral endplates (not shown) and/or the cartilage overlying the endplates. The frame 153 can take on a 3-D concave shape in this preferred position with the concavity generally directed toward the interior of the intervertebral disc and specifically a region occupied by the nucleus pulposus 20.

The bending stiffness of expander 153 can resist migration of the implant from this preferred position within the disc 15. The principle behind this stiffness-based stability is to place the regions of expander 153 with the greatest flexibility in the regions of the disc 153 with the greatest mobility or curvature. These flexible regions of expander 153 are surrounded by significantly stiffer regions. Hence, in order for the implant to migrate, a relatively stiff region of the expander must move into a relatively curved or mobile region of the disc.

For example, in order for expander 153 of Figure 34B to move around the inner circumference of annulus fibrosis 10 (i.e. from the posterior wall 21 onto the lateral 23 and/or anterior 27 wall), the stiff central region of expander 153 spanning the posterior wall 21 would have to bend around the acute curves of the posterior lateral corners of annulus 10. The stiffer this section of expander 153 is, the higher the forces necessary to force it around these corners and the less likely it is to migrate in this direction. This principle was also used in this embodiment to resist migration of fingers 162 away from the vertebral endplates: The slots 174 cut along the length of expander 153 create a central flexibility that encourages expander 153 to bend along an axis running through these slots as the posterior disc height increases and decreased during flexion and extension. In order for the fingers 162 to migrate away from the endplate, this central flexible region must move away from the posterior annulus 21 and toward an endplate. This motion is resisted by the greater stiffness of expander 153 in the areas directly inferior and superior to this central flexible region.

The expander 153 is preferably covered by a membrane that acts to further restrict the movement of materials through the frame and toward the outer periphery of the annulus fibrosis.

Figure 36 depicts an embodiment of the expander 153 of Figure 33A with an enlarged central strut 164 and a plurality of slots 174. This central strut 164 can have a uniform stiffness against superior-inferior 166 and 168 bending as shown in this embodiment. The strut 164 can alternatively have a varying stiffness along its height 178 to either promote or resist bending at a given location along the inner surface of the annulus 10.

Figures 37A-C depict a further embodiment of the frame or expander 153. This embodiment employs a central lattice 180 consisting of multiple, fine interconnected struts 182. Such a lattice 180 can provide a structure that minimizes bulging of the sealing means 51 under intradiscal pressures. The orientation and location of these struts 182 have been designed to give the barrier 12 a bend-axis along the central area of the expander height 172. The struts 182 support inferior 168 and superior 166 fingers 162 similar to previously described embodiments. However, these fingers 162 can have varying dimensions and stiffness along the length of the barrier 12. Such fingers 162 can be useful for helping the sealer 51 conform to uneven endplate geometries. Figure 37B illustrates the curved cross section 184 of the expander 153 of Figure 37A. This curve 184 can be an arc segment of a circle as shown. Alternatively, the cross section can be an ellipsoid segment or have a multitude of arc segments of different radii and centers. Figure 37C is a perspective view showing the three dimensional shape of the expander 153 of Figures 37A and 37B.

The embodiment of the frame 153 as shown in Figures 37A-C, can also be employed without the use of a covering membrane. The nucleus pulposus of many patients with low back pain or disc herniation can degenerate to a state in which the material properties of the nucleus cause it to behave much more like a solid than a gel. As humans age, the water content of the nucleus declines from roughly 88% to less than 75%. As this occurs, there is an increase in the cross linking of collagen within the disc resulting in a greater solidity of the nucleus. When the pore size or the largest open area of any given gap in the lattice depicted in Figures 37A, 37B, and 37C is between 0.05mm^2 (7.75x10^{-5}in^2) and 0.75mm^2 (1.16x10^{-3}in^2), the nucleus pulposus is unable to extrude through the lattice at pressures generated within the

disc (between 250KPa and 1.8MPa). The preferred pore size has been found to be approximately 0.15 mm^2 ($2.33x10^{-4}in^2$). This pore size can be used with any of the disclosed embodiments of the expander or any other expander that falls within the scope of the present invention to prevent movement of nucleus toward the outer periphery of the disc without the need for an additional membrane. The membrane thickness is preferably in a range of 0.025 mm to 2.5 mm.

Figure 38 depicts an expander 153 similar to that of Figure 37A without fingers. The expander 153 includes a central lattice 180 consisting of multiple struts 182.

Figures 39 through 41 depict another embodiment of the expander 153 of the present invention. These tubular expanders can be used in the barrier 12 embodiment depicted in Figure 31A. The sealer 51 can cover the expander 153 as shown in Figure 31A. Alternatively, the sealer 51 can cover the interior surface of the expander or an arc segment of the tube along its length on either the interior or exterior surface.

Figure 39 depicts an embodiment of a tubular expander 154. The superior 166 and inferior surfaces 168 of the tubular expander 154 can deploy against the superior and inferior vertebral endplates, respectively. The distance 186 between the superior 166 and inferior 168 surfaces of the expander 154 are preferably equal to or greater than the posterior disc height at the inner surface of the annulus 10. This embodiment has an annulus face 188 and nucleus face 190 as shown in Figures 39B, 39C and 39D. The annulus face 188 can be covered by the sealer 51 from the superior 166 to inferior 168 surface of the expander 154. This face 188 lies against the inner surface of the annulus 10 in its deployed position and can prevent egress of materials from within the disc 15. The primary purpose of the nucleus face 190 is to prevent migration of the expander 154 within the disc 15. The struts 192 that form the nucleus face 190 can project anteriorly into the nucleus 20 when the barrier 12 is positioned across the posterior wall of the annulus 10. This anterior projection can resist rotation of the tubular expansion means 154 about its long axis. By interacting with the nucleus 20, the struts 192 can further prevent migration around the circumference of the disc 15.

The struts 192 can be spaced to provide nuclear gaps 194. These gaps 194 can encourage the flow of nucleus pulposus 20 into the interior of the expander 154. This flow can insure full expansion of the barrier 12 within the disc 15 during deployment.

The embodiments of Figures 39, 40 and 41 vary by their cross-sectional shape. Figure 39 has a circular cross section 196 as seen in Figure 39C. If the superior-inferior height 186 of the expander 154 is greater than that of the disc 15, this circular cross section 196 can deform into an oval when deployed, as the endplates of the vertebrae compress the expander 154. The embodiment of the expander 154 shown in Figure 40 is preformed into an oval shape 198 shown in Figure 40C. Compression by the endplates can exaggerate the unstrained oval 198. This oval 198 can provide greater stability against rotation about a long axis of the expander 154. The embodiment of Figure 41B, 41C and 41D depict an 'egg-shaped' cross section 202, as shown in Figure 41C, that can allow congruity between the curvature of the expander 154 and the inner wall of posterior annulus 10. Any of a variety of alternate cross sectional shapes can be employed to obtain a desired fit or expansion force without deviating from the spirit of the present invention.

Figures 40E, 40F, and 40I depict the expander 154 of Figures 40A-D having a sealing means 51 covering the exterior surface of the annulus face 188. This sealing means 51 can be held against the endplates and the inner surface of the posterior annulus by the expander 154 in its deployed state.

Figures 40G and 40H depict the expander 154 of Figure 40B with a sealer 51 covering the interior surface of the annulus face 188. This position of the sealer 51 can allow the expander 154 to contact both the vertebral endplates and inner surface of the posterior annulus. This can promote ingrowth of tissue into the expander 154 from outside the disc 15. Combinations of sealer 51 that cover all or part of the expander 154 can also be employed without deviating from the scope of the present invention. The expander 154 can also have a small pore size thereby allowing retention of a material such as a nucleus pulposus, for example, without the need for a sealer as a covering.

Figures 42A-D depict cross sections of a preferred embodiment of sealing means 51 and enlarging means 53. Sealing means 51 has internal cavity 17 and opening 8 leading from its outer surface into internal cavity 17. Enlarger 53 can be inserted through opening 8 and into internal cavity 17.

Figures 43A and 43B depict an alternative configuration of enlarger 53. Fixation region 4 extends through opening 8 in sealing means 51. Fixation region 4 has a through-hole that can facilitate fixation of enlarger 53 to tissues surrounding defect 16.

Figures 44A and 44B depict an alternative shape of the barrier. In this embodiment, sealing means 51, enlarger 53, or both have a curvature with radius R. This curvature can be used in any embodiment of the present invention and may aid in conforming to the curved inner circumference of annulus fibrosis 10.

Figure 45 is a section of a device used to affix sealing means 51 to tissues surrounding a defect. In this figure, sealing means 51 would be positioned across interior aspect 50 of defect 16. The distal end of device 110' would be inserted through defect 16 and opening 8 into the interior cavity 17. On the right side of this figure, fixation dart 25 has been passed from device 110', through a wall of sealing means 51 and into tissues surrounding sealing means 51. On the right side of the figure, fixation dart 25 is about to be passed through a wall of sealing means 51 by advancing pusher 111 relative to device 110' in the direction of the arrow.

Figure 46 depicts the use of thermal device 200 to heat sealing means 51 and adhere it to tissues surrounding a defect. In this figure, sealing means 51 would be positioned across the interior aspect 36 of a defect 16. The distal end of thermal device 200 would be inserted through the defect and opening 8 into interior cavity 17. In this embodiment, thermal device 200 employs at its distal end resistive heating element 210 connected to a voltage source by wires 220. Covering 230 is a non-stick surface such as Teflon tubing that ensures the ability to remove device 200 from interior cavity 17. In this embodiment, device 200 would be used to heat first one half, and then the other half of sealing means 51.

Figure 47 depicts an expandable thermal element, such as a balloon, that can be used to adhere sealing means 51 to tissues surrounding a defect. As in Figure 18,

the distal end of device 130 can be inserted through the defect and opening 8 into interior cavity 17, with balloon 150' on the distal end device 130 in a collapsed state. Balloon 150' is then inflated to expanded state 150, expanding sealing means 51. Expanded balloon 150 can heat sealing means 51 and surrounding tissues by inflating it with a heated fluid or by employing RF electrodes. In this embodiment, device 130 can be used to expand and heat first one half, then the other half of sealing means 51.

Figure 48 depicts an alternative embodiment to device 130. This device employs an elongated, flexible balloon 150' that can be inserted into and completely fill internal cavity 17 of sealing means 51 prior to inflation to an expanded state 150. Using this embodiment, inflation and heating of sealing means 51 can be performed in one step.

Figures 49A through 49G illustrate a method of implanting an intradiscal implant. An intradiscal implant system consists of an intradiscal implant 400, a delivery device or cannula 402, an advancer 404 and at least one control filament 406. The intradiscal implant 400 is loaded into the delivery cannula 402 which has a proximal end 408 and a distal end 410. Figure 49A illustrates the distal end 410 advanced into the disc 15 through an anulotomy 416. This anulotomy 416 can be through any portion of the annulus 10, but is preferably at a site proximate to a desired, final implant location. The implant 400 is then pushed into the disc 15 through the distal end 410 of the cannula 402 in a direction that is generally away from the desired, final implant location as shown in Figure 49B. Once the implant 400 is completely outside of the delivery cannula 402 and within the disc 15, the implant 400 can be pulled into the desired implant location by pulling on the control filament 406 as shown in Figure 49C. The control filament 406 can be secured to the implant 400 at any location on or within the implant 400, but is preferably secured at least at a site 414 or sites on a distal portion 412 of the implant 400, i.e. that portion that first exits the delivery cannula 402 when advanced into the disc 15. These site or sites 414 are generally furthest from the desired, final implant location once the implant has been fully expelled from the interior of the delivery cannula 402.

Pulling on the control filament 406 causes the implant 400 to move toward the anulotomy 416. The distal end 410 of the delivery cannula 402 can be used to direct the proximal end 420 of the implant 400 (that portion of the implant 400 that is last to be expelled from the delivery cannula 402) away from the anulotomy 416 and toward an inner aspect of the annulus 10 nearest the desired implant location. Alternately, the advancer 404 can be used to position the proximal end of the implant toward an inner aspect of the annulus 20 near the implant location, as shown in Figure 49E. Further pulling on the control filament 406 causes the proximal end 426 of the implant 400 to dissect along the inner aspect of the annulus 20 until the attachment site 414 or sites of the guide filament 406 to the implant 400 has been pulled to the inner aspect of the anulotomy 416, as shown in Figure 49D. In this way, the implant 400 will extend at least from the anulotomy 416 and along the inner aspect of the annulus 10 in the desired implant location, illustrated in Figure 49F.

The implant 400 can be any of the following: nucleus replacement device, nucleus augmentation device, annulus augmentation device, annulus replacement device, the barrier of the present invention or any of its components, drug carrier device, carrier device seeded with living cells, or a device that stimulates or supports fusion of the surrounding vertebra. The implant 400 can be a membrane which prevents the flow of a material from within the annulus fibrosis of an intervertebral disc through a defect in the disc. The material within the annulus fibrosis can be, for example, a nucleus pulposus or a prosthetic augmentation device, such as hydrogel. The membrane can be a sealer. The implant 400 can be wholly or partially rigid or wholly or partially flexible. It can have a solid portion or portions that contain a fluid material. It can comprise a single or multitude of materials. These materials can include metals, polymers, gels and can be in solid or woven form. The implant 400 can either resist or promote tissue ingrowth, whether fibrous or bony.

The cannula 402 can be any tubular device capable of advancing the implant 400 at least partially through the annulus 10. It can be made of any suitable biocompatible material including various known metals and polymers. It can be wholly or partially rigid or flexible. It can be circular, oval, polygonal, or irregular

in cross section. It must have an opening at least at its distal end 410, but can have other openings in various locations along its length.

The advancer 404 can be rigid or flexible, and have one of a variety of cross sectional shapes either like or unlike the delivery cannula 402. It may be a solid or even a column of incompressible fluid, so long as it is stiff enough to advance the implant 400 into the disc 15. The advancer 404 can be contained entirely within the cannula 402 or can extend through a wall or end of the cannula to facilitate manipulation.

Advancement of the implant 400 can be assisted by various levers, gears, screws and other secondary assist devices to minimize the force required by the surgeon to advance the implant 400. These secondary devices can further give the user greater control over the rate and extent of advancement into the disc 15.

The guide filament 406 may be a string, rod, plate, or other elongate object that can be secured to and move with the implant 400 as it is advanced into the disc 15. It can be constructed from any of a variety of metals or polymers or combination thereof and can be flexible or rigid along all or part of its length. It can be secured to a secondary object 418 or device at its end opposite that which is secured to the implant 400. This secondary device 418 can include the advancer 404 or other object or device that assists the user in manipulating the filament. The filament 406 can be releasably secured to the implant 400, as shown in Figure 49G or permanently affixed. The filament 406 can be looped around or through the implant. Such a loop can either be cut or have one end pulled until the other end of the loop releases thc implant 400. It may be bonded to the implant 400 using adhesive, welding, or a secondary securing means such as a screw, staple, dart, etc. The filament 406 can further be an elongate extension of the implant material itself. If not removed following placement of the implant, the filament 406 can be used to secure the implant 400 to surrounding tissues such as the neighboring annulus 10, vertebral endplates, or vertebral bodies either directly or through the use of a dart, screw, staple, or other suitable anchor.

Multiple guide filaments can be secured to the implant 400 at various locations. In one preferred embodiment, a first or distal 422 and a second or

proximal 424 guide filament are secured to an elongate implant 400 at or near its distal 412 and proximal 420 ends at attachment sites 426 and 428, respectively. These ends 412 and 420 correspond to the first and last portions of the implant 400, respectively, to be expelled from the delivery cannula 402 when advanced into the disc 15. This double guide filament system allows the implant 400 to be positioned in the same manner described above in the single filament technique, and illustrated in Figures 50A-C. However, following completion of this first technique, the user may advance the proximal end 420 of the device 400 across the annulotomy 416 by pulling on the second guide filament 424, shown in Figure 50D. This allows the user to controllably cover the annulotomy 416. This has numerous advantages in various implantation procedures. This step may reduce the risk of herniation of either nucleus pulposus 20 or the implant itself. It may aid in sealing the disc, as well as preserving disc pressure and the natural function of the disc. It may encourage ingrowth of fibrous tissue from outside the disc into the implant. It may further allow the distal end of the implant to rest against annulus further from the defect created by the annulotomy. Finally, this technique allows both ends of an elongate implant to be secured to the disc or vertebral tissues.

Both the first 422 and second 424 guide filaments can be simultaneously tensioned, as shown in Figure 50E, to ensure proper positioning of the implant 400 within the annulus 10. Once the implant 400 is placed across the annulotomy, the first 422 and second 424 guide filaments can be removed from the input 400, as shown in Figure 50F. Additional control filaments and securing sites may further assist implantation and/or fixation of the intradiscal implants.

In another embodiment of the present invention, as illustrated in Figures 51A-C, an implant guide 430 may be employed to aid directing the implant 400 through the annulotomy 416, through the nucleus pulposus 10, and/or along the inner aspect of the annulus 10. This implant guide 430 can aid in the procedure by dissecting through tissue, adding stiffness to the implant construct, reducing trauma to the annulus or other tissues that can be caused by a stiff or abrasive implant, providing 3-D control of the implants orientation during implantation, expanding an expandable implant, or temporarily imparting a shape to the implant that is

beneficial during implantation. The implant guide 430 can be affixed to either the advancer 404 or the implant 406 themselves. In a preferred embodiment shown in Figures 52A and 52B, the implant guide 430 is secured to the implant 400 by the first 424 and second 426 guide filaments of the first 426 and the second 428 attachment sites, respectively. The guide filaments 424 and 426 may pass through or around the implant guide 430. In this embodiment, the implant guide 430 may be a thin, flat sheet of biocompatible metal with holes passing through its surface proximate to the site or sites 426 and 428 at which the guide filaments 422 and 424 are secured to the implant 400. These holes allow passage of the securing filament 422 and 424 through the implant guide 430. Such an elongated sheet may run along the implant 400 and extend beyond its distal end 412. The distal end of the implant guide 430 may be shaped to help dissect through the nucleus 10 and deflect off of the annulus 10 as the implant 400 is advanced into the disc 15. When used with multiple guide filaments, such an implant guide 430 can be used to control rotational stability of the implant 400. It may also be used to retract the implant 400 from the disc 15 should this become necessary. The implant guide 430 may also extend beyond the proximal tip 420 of the implant 400 to aid in dissecting across or through the annulus 10 proximate to the desired implantation site.

The implant guide 430 is releasable from the implant 400 following or during implantation. This release may be coordinated with the release of the guide filaments 422 and 424. The implant guide 430 may further be able to slide along the guide filaments 422 and 424 while these filaments are secured to the implant 400.

Various embodiments of the barrier 12 or implant 400 can be secured to tissues within the intervertebral disc 15 or surrounding vertebrae. It can be advantageous to secure the barrier means 12 in a limited number of sites while still insuring that larger surfaces of the barrier 12 or implant juxtapose the tissue to which the barrier 12 is secured. This is particularly advantageous in forming a sealing engagement with surrounding tissues.

Figures 53-57 illustrate barriers having stiffening elements 300. The barrier 12 can incorporate stiffening elements 300 that run along a length of the implant required to be in sealing engagement. These stiffening elements 300 can be one of a

variety of shapes including, but not limited to, plates 302, rods 304, or coils. These elements are preferably stiffer than the surrounding barrier 12 and can impart their stiffness to the surrounding barrier. These stiffening elements 300 can be located within an interior cavity formed by the barrier. They can further be imbedded in or secured to the barrier 12.

Each stiffening element can aid in securing segments of the barrier 12 to surrounding tissues. The stiffening elements can have parts 307, including through-holes, notches, or other indentations for example, to facilitate fixation of the stiffening element 300 to surrounding tissues by any of a variety of fixation devices 306. These fixation devices 306 can include screws, darts, dowels, or other suitable means capable of holding the barrier 12 to surrounding tissue. The fixation devices 306 can be connected either directly to the stiffening element 300 or indirectly using an intervening length of suture, cable, or other filament for example. The fixation device 306 can further be secured to the barrier 12 near the stiffening element 300 without direct contact with the stiffening element 300.

The fixation device 306 can be secured to or near the stiffening element 300 at opposing ends of the length of the barrier 12 required to be in sealing engagement with surrounding tissues. Alternatively, one or a multitude of fixation devices 306 can be secured to or near the stiffening element 300 at a readily accessible location that may not be at these ends. In any barrier 12 embodiment with an interior cavity 17 and an opening 8 leading thereto, the fixation sites may be proximal to the opening 8 to allow passage of the fixation device 306 and various instruments that may be required for their implantation.

Figures 53A and 53B illustrate one embodiment of a barrier 12 incorporating the use of a stiffening element 300. The barrier 12 can be a plate and screw barrier 320. In this embodiment, the stiffening element 300 consists of two fixation plates, superior 310 and inferior 312, an example of which is illustrated in Figures 54A and 54B with two parts 308 passing through each plate. The parts 308 are located proximal to an opening 8 leading into an interior cavity 17 of the barrier 12. These parts 8 allow passage of a fixation device 306 such as a bone screw. These screws can be used to secure the barrier means 12 to a superior 50 and inferior 50' vertebra.

As the screws are tightened against the vertebral endplate, the fixation plates 310, 312 compress the intervening sealing means against the endplate along the superior and inferior surfaces of the barrier 12. This can aid in creating a sealing engagement with the vertebral endplates and prevent egress of materials from within the disc 15. As illustrated in Figures 53A and 53B, only the superior screws have been placed in the superior plate 310, creating a sealing engagement with the superior vertebra.

Figures 55A and 55B illustrate another embodiment of a barrier 12 having stiffening elements 300. The barrier 12 can be an anchor and rod barrier 322. In this embodiment, the stiffening elements 300 consist of two fixation rods 304, an example of which is shown in Figures 56A and 56B, imbedded within the barrier 12. The rods 304 can include a superior rod 314 and an inferior rod 316. Sutures 318 can be passed around these rods 314 and 316 and through the barrier means 10. These sutures 318 can in turn, be secured to a bone anchor or other suitable fixation device 306 to draw the barrier 12 into sealing engagement with the superior and inferior vertebral endplates in a manner similar to that described above. The opening 8 and interior cavity 17 of the barrier 12 are not required elements of the barrier 12.

Figure 57 illustrates the anchor and rod barrier 322, described above, with fixation devices 306 placed at opposing ends of each fixation rod 316 and 318. The suture 18 on the left side of the superior rod 318 has yet to be tied.

Various methods may be employed to decrease the forces necessary to maneuver the barrier 12 into a position along or within the lamellae of the annulus fibrosis 10. Figures 58A, 58B, 59A and 59B depict two preferred methods of clearing a path for the barrier 12.

Figures 58A and 58B depict one such method and an associated dissector device 454. In these figures, the assumed desired position of the implant is along the posterior annulus 452. In order to clear a path for the implant, a hairpin dissector 454 can be passed along the intended implantation site of the implant. The hairpin dissector 454 can have a hairpin dissector component 460 having a free end 458. The dissector can also have an advancer 464 to position the dissector component 460 within the disc 15. The dissector 454 can be inserted through cannula 456 into an

opening 462 in the annulus 10 along an access path directed anteriorly or anterior-medially. Once a free-end 458 of the dissector component 460 is within the disc 15, the free-end 458 moves slightly causing the hairpin to open, such that the dissector component 460 resists returning into the cannula 456. This opening 462 can be caused by pre-forming the dissector to the opened state. The hairpin dissector component 460 can then be pulled posteriorly, causing the dissector component 460 to open, further driving the free-end 458 along the posterior annulus 458. This motion clears a path for the insertion of any of the implants disclosed in the present invention. The body of dissector component 460 is preferably formed from an elongated sheet of metal. Suitable metals include various spring steels or nickel titanium alloys. It can alternatively be formed from wires or rods.

Figures 59A and 59B depict another method and associated dissector device 466 suitable for clearing a path for implant insertion. The dissector device 466 is shown in cross section and consists of a dissector component 468, an outer cannula 470 and an advancer or inner push rod 472. A curved passage or slot 474 is formed into an intradiscal tip 476 of outer cannula 470. This passage or slot 474 acts to deflect the tip of dissector component 468 in a path that is roughly parallel to the lamellae of the annulus fibrosis 10 as the dissector component 468 is advanced into the disc 15 by the advancer. The dissector component 468 is preferably formed from a superelastic nickel titanium alloy, but can be constructed of any material with suitable rigidity and strain characteristics to allow such deflection without significant plastic deformation. The dissector component 468 can be formed from an elongated sheet, rods, wires or the like. It can be used to dissect between the annulus 10 and nucleus 20, or to dissect between layers of the annulus 10.

Figures 60A-C depict an alternate dissector component 480 of Figures 59A and 59B. Only the intradiscal tip 476 of device 460 and regions proximal thereto are shown in these figures. A push-rod 472 similar to that shown in Figure 59A can be employed to advance dissector 480 into the disc 15. Dissector 480 can include an elongated sheet 482 with superiorly and inferiorly extending blades (or "wings") 484 and 486, respectively. This sheet 482 is preferably formed from a metal with a large elastic strain range such as spring steel or nickel titanium alloy. The sheet 482 can

have a proximal end 488 and a distal end 490. The distal end 490 can have a flat portion which can be flexible. A step portion 494 can be located between the distal end 490 and the proximal end 488. The proximal end 488 can have a curved shape. The proximal end can also include blades 484 and 486.

In the un-deployed state depicted in Figures 60A and 60B, wings 484 and 486 are collapsed within outer cannula 470 while elongated sheet 482 is captured within deflecting passage or slot 474. As the dissector component 480 is advanced into a disc 15, passage or slot 478 directs the dissector component 480 in a direction roughly parallel to the posterior annulus (90 degrees to the central axis of sleeve 470 in this case) in a manner similar to that described for the embodiment in Figures 59A and 59B. Wings 484 and 486 open as they exit the end of sleeve 470 and expand toward the vertebral endplates. Further advancement of dissector component 480 allows the expanded wings 484 and 486 to dissect through any connections of nucleus 20 or annulus 10 to the endplates that may present an obstruction to subsequent passage of the implants of the present invention. When used to aid in the insertion of a barrier, the dimensions of dissector component 480 should approximate those of the barrier such that the minimal amount of tissue is disturbed while reducing the forces necessary to position the barrier in the desired location.

While this invention has been particularly shown and described with references to preferred embodiments thereof, it will be understood by those skilled in the art that various changes in form and details may be made therein without departing from the scope of the invention encompassed by the appended claims.

CLAIMS

What is claimed is:

1. A prosthesis for implantation into the intervertebral disc comprising a barrier that extends circumferentially within an annulus fibrosis of the intervertebral disc.

2. The prosthesis of Claim 1 wherein the barrier comprises a frame.

3. The prosthesis of Claim 2 further comprising an enlarging element that alters a shape of the frame.

4. The prosthesis of Claim 1 further comprising a fixation device, the fixation device attaching the prosthesis to a portion of an intervertebral body.

5. The prosthesis of Claim 4 wherein the fixation device comprises a bone anchor.

6. The prosthesis of Claim 2 wherein the barrier further comprises a membrane, the membrane covering at least a portion of the frame.

7. The prosthesis of Claim 4 wherein the fixation device comprises a soft tissue anchor.

8. The prosthesis of Claim 6 wherein the membrane is constructed from a material selected from the group consisting of synthetic polyamide, synthetic polyester polyethylene, collagen, PTFE, and e-PTFE.

9. The prosthesis of Claim 6 wherein the membrane is woven.

10. The prosthesis of Claim 6 wherein the membrane is woven.

11. The prosthesis of Claim 1 wherein the barrier has a central strut along a first axis and a plurality of radial members extending from the strut.

12. The prosthesis of Claim 11 wherein the strut has one or more openings.

13. The prosthesis of Claim 11 wherein the strut has a plurality of radial members extending from opposite sides of the strut.

14. The prosthesis of Claim 2 wherein the frame comprises a material selected from the group consisting of an alloy of nickel and titanium, stainless steel, cobalt chrome, titanium, polyethylene, and silicone rubber.

15. The prosthesis of Claim 1 further comprising a spacer including a flexible solid that increases a volume of material within the disc and thereby prevents a loss in height of the disc.

16. The prosthesis of Claim 11 wherein the radial members have a varying width.

17. A prosthesis for implantation into an intervertebral disc, the disc having an annulus fibrosis defining the periphery of the disc, the annulus fibrosis having an inner surface in contact with the nucleus pulposus, the inner surface having a posterior surface and a left and right lateral surface, the prosthesis comprising a barrier having a length that extends along at least a portion of the posterior surface and at least a portion of the lateral surface.

18. The prosthesis of Claim 17 wherein the prosthesis comprises the barrier prevents migration of material toward an outer periphery of the disc.

19. The prosthesis of Claim 18 wherein the barrier comprises a frame.

20. The prosthesis of Claim 18 wherein the barrier comprises a membrane.

21. The prosthesis of Claim 19 wherein the frame comprises an enlarging component.

22. A prosthesis for implantation into an intervertebral disc wherein the prosthesis comprises a barrier that spans a region of an inner aspect of the posterior the annulus fibrosis of the disc and extends onto a first end plate and a second end plate of the two vertebral bodies located at ends of the annulus fibrosis.

23. The prosthesis of Claim 22 wherein the prosthesis comprises a frame.

24. The prosthesis of Claim 22 wherein the frame comprises an enlarging component.

25. The prosthesis of Claim 23 wherein the prosthesis further comprises a membrane covering at least a portion of the frame.

26. The prosthesis of Claim 25 wherein the membrane has a thickness in a range between 0.025 mm and 2.5 mm.

27. A prosthesis for implantation into a intervertebral disc comprising a frame and a membrane mounted to the frame.

28. The prosthesis of Claim 27 wherein the frame comprises an expander which expands the membrane from a compressed state to an enlarged state.

29. The prosthesis of Claim 27 wherein the prosthesis further comprises a fixation device.

30. The prosthesis of Claim 27 wherein the frame comprises a semi-circular cross-section.

31. The prosthesis of Claim 27 wherein the frame has a circular cross-section.

32. The prosthesis of Claim 27 wherein the frame comprises an oval cross-section.

33. The prosthesis of Claim 27 wherein the prosthesis further comprises at least one dissecting surface.

34. The prosthesis of Claim 27 wherein the membrane comprises a sealer.

35. The prosthesis of Claim 27 further comprising at least one guide filament wherein the at least one guide filament allows positioning of the prosthesis within the intervertebral disc.

36. The prosthesis of Claim 35 wherein the at least one guide filament comprises a proximal guide filament and a distal guide filament.

37. The prosthesis of Claim 27 wherein the prosthesis is a component of a kit further comprising a delivery device, the delivery device including of an implant guide.

38. The prosthesis of Claim 37 wherein the implant guide comprises a distal end having a dissector.

39. The prosthesis of Claim 27 wherein the membrane comprises a drug delivery material.

40. A prosthesis for implantation into an intervertebral disc comprising:

a barrier having a membrane; and

a thermal device wherein heating of the membrane by the thermal device adheres the membrane to intervertebral disc tissue.

41. The prosthesis of Claim 40 wherein the barrier defines a cavity for insertion of the thermal device.

42. The prosthesis of Claim 40 wherein the thermal device comprises a non-stick surface.

43. The prosthesis of Claim 40 wherein the thermal device comprises a balloon.

44. A prosthesis for implantation into an intervertebral disc comprising a barrier wherein the barrier has at least one control filament.

45. The prosthesis of Claim 44 wherein the filament further releasably secures the prosthesis to an implant guide.

46. The prosthesis of Claim 44 wherein the barrier has a distal end and a proximal end and at least one control filament comprises a first control filament and a second control filament.

47. The prosthesis of Claim 46 wherein the first control filament attaches to a distal attachment site of the barrier.

48. The prosthesis of Claim 46 wherein the second control filament attaches to a proximal attachment site of the barrier.

49. The prosthesis of Claim 44 wherein the at least one control filament is releasably secured to the barrier.

50. A prosthesis for implantation into an intervertebral disc comprising:
an anchor;
a support member; and
a connection member attached to the anchor and attached to the support member.

51. The prosthesis of Claim 50 wherein the anchor attaches to a vertebral body.

52. The prosthesis of Claim 50 wherein the anchor attaches to the annulus fibrosis.

53. The prosthesis of Claim 50 wherein the support member attaches to a herniated segment of the annulus fibrosis.

54. The prosthesis of Claim 50 wherein the support member attaches posterior to a herniated segment of an annulus fibrosis.

55. The prosthesis of Claim 50 wherein the anchor, the support member and the connection member comprise a unitary element.

56. The prosthesis of Claim 50 further comprising an augmentation device wherein the augmentation device comprises a flexible solid that acts to increase the overall volume of material within the disc and thereby prevents a loss in height of the disc.

57. The prosthesis of Claim 56 wherein the augmentation device further comprises a channel wherein the channel surrounds the connection member.

58. The prosthesis of Claim 56 wherein the anchor, the support member, the connection member and the augmentation material comprise a single construct.

59. The prosthesis of Claim 50 wherein there is:

a first vertebra having an anterior end and a posterior end;

a second vertebra having an anterior end and a posterior end, said second vertebra adjoining said first vertebra, forming an intervertebral space between said first and said second vertebra, said anterior end of said first vertebra aligned with said anterior end of said second vertebra, and said posterior end of said first vertebra aligned with said posterior end of said second vertebra;

an intervertebral disc having an annulus fibrosis surrounding a central region, said intervertebral disc positioned between said first and second vertebra within the intervertebral disc space; and

an *in vivo* disc herniation constraining device including the anchor, the support member, and connection member coupled there between; said anchor being fixedly coupled to an anterior portion of at least one of said first vertebra or said second vertebra or annulus fibrosis, and said support member coupled to a portion of said annulus fibrosis in a position posterior to said central region; and said connection member extending between said anchor and said support member whereby said connection member is maintained between said anchor and said support member.

60. The prosthesis of Claim 1 wherein the barrier has a concave shape.

61. The prosthesis of Claim 1 wherein the barrier has a thickness in a range between 0.1 mm and 0.6 mm.

62. The prosthesis of Claim 6 wherein wherein the membrane has a thickness in a range between 0.025 mm and 2.5 mm.

63. The prosthesis of Claim 50 wherein an *in vivo* placement of the prosthesis includes a first vertebra having an anterior end and a posterior end;

a second vertebra having an anterior end and a posterior end, said second vertebra adjoining said first vertebra, forming an intervertebral space between said first and said second vertebra, said anterior end of said first vertebra aligned with said anterior end of said second vertebra, and said posterior end of said first vertebra aligned with said posterior end of said second vertebra;

an intervertebral disc having an annulus fibrosis surrounding a central region pulposus, said intervertebral disc positioned between said first and second vertebra substantially within the intervertebral disc space; and

a disc support device including the anchor, a spacer support member material, and a connection member coupled there between; said anchor being fixedly coupled to an anterior portion of at least one of said first veterbra or said second vertebra or annulus fibrosis, and said material positioned in said intervertebral disc space between said adjacent vertebra; and said connection member extending between said anchor and said spacer material whereby said connection member restrains movement of said spacer material to be substantially within said intervertebral disc space.

64. The prosthesis of Claim 17 wherein the prosthesis has a concave shape.

65. The prosthesis of Claim 17 wherein the barrier comprises a frame having a thickness in a range between 0.1 mm and 0.6 mm.

66. A method of repairing a herniated disc comprising the steps of:

displacing at least a portion of the herniated segment to within the pre-herniated borders of the disc; and

anchoring at least a portion of the displaced herniated segment to a site.

67. The method of Claim 66 further comprising:

establishing a first anchoring means in at least a portion of the herniated segment of disc;

establishing a second anchoring means in a site;

providing at least one connection means which joins the first and second anchoring means;

applying tension between the first and second anchoring means along the connection means to cause the herniated segment or to move within the pre-herniated borders of the disc.

68. The method of Claim 66 comprising inserting further biocompatible material into the disc space to aid in restoring disc height.

69. The method of Claim 67 wherein said site is one or more of the following:

the superior or inferior vertebral body; and

the anterior, anterior medial or anterior lateral annulus fibrosis.

70. A method of supporting a nucleus pulposus of an intervertebral disc in a spine comprising the steps of:

providing a first anchoring means in a site in a spine;

providing at least one connection means leading from said anchoring means that at least in part traverses a disc space;

inserting into the disc space at least one plug of biocompatible material on said connection means;

terminating said connections means so as to prevent said plug or plugs from moving off said connection means and/or out of said disc space.

71. The method of Claim 70 further comprising providing a connection means that closes an opening in the annulus fibrosis.

72. The method of Claim 70 further comprising terminating the connection means by affixing a second anchoring means to the connection means and further affixing said second anchoring means to a site in the spine.

73. The method of Claim 70 further comprising providing a capping means that is affixed to the connection means.

74. The method of Claim 70 further comprising connection an un-terminated end of the connection means to the first anchoring means.

75. The method of Claim 70 further comprising affixing the to said connection means so as to be insertable into the disc space along said connection means after placement of said first anchoring means.

76. A method of supporting a nucleus pulposus of an intervertebral disc in a spine comprising the steps of:

inserting a flexible biocompatible material into the disc space, said material being attached to an anchoring means;

anchoring said material to a site within the FSU with said anchoring means.

77. The method of Claim 76 further comprising supporting an anterior, anterior medial, anterior lateral, or lateral portion of an annulus fibrosis of the disc.

78. The method of Claim 76 further comprising said material that is a fibrous material including either collagen or cellulous.

79. The method of Claim 76 further comprising providing said material that is hydrogel.

80. A method of closing a defect in an annulus of an intervertebral disc, said intervertebral disc being part of a spine including the steps of:
inserting a barrier through an opening into a disc;
positioning said barrier relative to said defect such that said barrier obstructs passage of material from the interior of said disc into said defect.

81. The method of Claim 80 wherein said opening is spacially separated from said defect.

82. The method of Claim 80 further comprising:
inserting an expandable barrier into the interior of said disc, the barrier comprising a frame and a membrane;
positioning said barrier proximate to said defect; and
expanding said barrier such that said barrier obstructs passage of materials from the interior of said disc into said defect.

83. The method of Claim 80 wherein said annulus has multiple layers, said method involving the steps of:
inserting a first portion of a barrier between at least two layers of said annulus on a first side of said defect; and
inserting a second portion of said barrier between at least two layers of said annulus fibrosis on a second side of said defect, such that said barrier spans said defect and is maintained in position at least in part by the annulus fibrosis on either side of said defect, said barrier acting to obstruct passage of material from the interior of said disc to the exterior of said disc through said defect.

84. A method of sealing a defect in a structure separating two anatomic regions of a body, said defect having an interior aspect and an exterior aspect, said interior aspect facing a first of said two anatomic regions and said exterior aspect facing a second of said two anatomic regions, said interior aspect defining a region between said structure and a tissue within said first anatomic region, said wall and said tissue being in contact, said method involving the steps of:

inserting a dissection tool into said first anatomic region, said dissection tool comprising at least a barrier releasably secured to said dissection tool;

dissecting a space between said wall and said tissue on said interior aspect of said defect with said dissection tool;

deploying said barrier into said space; and

removing said dissection tool.

85. The method of Claim 84 wherein said first anatomic region includes the annulus fibrosis and a superior and inferior vertebral endplates of an intervertebral disc, said second anatomic region being outside the annulus fibrosis.

86. A disc prosthesis that acts to bear loads passing through an intervertebral disc and to seal a defect in an annulus fibrosis of said disc, said defect having an interior aspect facing the interior of said disc, said disc prosthesis comprising:

an elastic spacer dimensioned to be inserted into the interior of said disc through a defect in said annulus fibrosis, said spacer having a compliant structure that fills at least a portion of the interior of said disc; and

a barrier dimensioned to extend across the interior aspect of said defect and obstruct the passage of material from the interior of said disc into said defect.

87. A system for sealing a defect in a soft tissue of a living being, said system comprising:

an expandable barrier formed at least in part from a material capable of adhering to surrounding tissues upon the application of heat to said barrier and said surrounding tissues;

a deployment device, said deployment device positionable at least in part within an interior cavity, said deployment device comprising at least a balloon capable of inflating from a compressed state to an expanded state, and a thermal element capable of increasing the temperature of said barrier and said surrounding tissues.

88. A prosthesis for implantation into an intervertebral disc comprising a barrier that can be inserted at least in part between the nucleus pulposus and the annulus fibrosis of the intervertebral disc.

89. The prosthesis of Claim 88 wherein the barrier comprises a frame and a membrane.

90. The prosthesis of Claim 89 wherein the frame comprises an enlarging component.

91. The prosthesis of Claim 88 further comprising a fixation device wherein the fixation device attaches the prosthesis to the intervertebral disc or surrounding vertebrae.

92. The prosthesis of Claim 91 wherein the fixation device comprises a bone anchor.

93. The prosthesis of Claim 91 wherein the fixation device comprises a soft tissue anchor.

94. The prosthesis of Claim 91 further comprising a connector whereby the connector attaches the fixation device to the barrier.

95. The prosthesis of Claim 88 further comprising an augmentation device wherein the augmentation device comprises a flexible solid that acts to increase the overall volume of material within the disc and thereby prevents a loss in disc height.

96. A delivery tool for delivering a prosthetic implant into an intervertebral disc comprising:
a delivery cannula;
an advancer mounted within the delivery cannula; and
an implant guide mounted to the advancer.

97. The delivery tool of Claim 96 wherein the implant guide comprises a dissector that dissects tissue of the intervertebral disc.

98. A prosthesis for implantation into an intervertebral disc comprising a barrier; and a frame located within the barrier.

99. The prosthesis of Claim 98 wherein the frame comprises at least one rod.

100. The prosthesis of Claim 98 wherein the frame comprises at least one plate.

101. The prosthesis of Claim 98 further comprising at least one fixation device, wherein the fixation device attaches the frame to at least one vertebral body surrounding the disc, and wherein the frame is substantially rigid.

102. A prosthesis for implantation into an intervertebral disc, the prosthesis having a concave surface positioned along at least a portion of an inner

circumference of the disc, the concave surface being directed toward an interior of the disc.

103. The prosthesis of Claim 102 wherein the prosthesis comprises a central strut having a plurality of radial members.

104. A pre-dissection tool for an intervertebral disc comprising:
a distal end; and
a proximal region having a blade.

105. The tool of Claim 104 wherein the distal end is flexible and the proximal region is stiff relative to the distal end.

106. The tool of Claim 104 wherein the distal end has a cutting surface.

107. The tool of Claim 104 further comprising a plurality of blades.

108. The tool of Claim 104 wherein the proximal region has a curved cross-sectional shape.

109. A method of making a prosthesis for insertion into a intervertebral disc comprising forming a self-expanding frame, wherein the frame has a plurality of pores.

110. The method of Claim 109 wherein the pores have an average size in a range of $0.05mm^2$ to $0.75mm^2$.

111. An intervertebral disc dissector comprising:
a dissector component wherein the dissector component locates an inner surface of an intervertebral disc;
an advancer attached to the dissector component; and

a cannula that houses the dissector component and at least a portion of the advancer.

112. The disc dissector of Claim 111wherein the dissector component comprises a generally hairpin-shaped dissector.

113. The disc dissector of Claim 111wherein the cannula further comprises a curved passage or slot wherein the passage or slot deflects the dissector component into a path that is substantially parallel to the lamellae of the annulus fibrosis.

114. The disc dissector of Claim 113 wherein the dissector component comprises one or more wings wherein the wings dissect connections between at least some portion of the annulus fibrosis and/or nucleus pulposus and the vertebral endplates.

115. A prosthesis for implantation into an intervertebral disc cavity comprising a membrane that obstructs the migration of material from within the cavity toward the periphery of the disc.

116. The prosthesis of Claim 115 further comprising an expander that expands the membrane from a compressed state to an enlarged state.

117. The prosthesis of Claim 115 further comprising a fixation device that restricts motion of the membrane within the intervertebral disc.

118. The prosthesis of Claim 115 further comprising at least one guide filament wherein the at least one guide filament allows positioning of the membrane within the intervertebral disc.

119. The prosthesis of Claim 118 wherein the at least one guide filament comprises a proximal guide filament and a distal guide filament.

120. The prosthesis of Claim 115 further comprising a delivery device consisting of an implant guide.

121. The prosthesis of Claim 120 wherein the implant guide comprises a distal end having a dissector.

122. The prosthesis of Claim 115 further comprising a frame having a semi-circular cross-sectional shape.

123. The prosthesis of Claim 115 further comprising a frame having

124. The prosthesis of Claim 115 wherein the membrane further comprises a frame having at least one dissecting surface.

125. The prosthesis of Claim 115 wherein the material comprises nucleus pulposus.

126. The prosthesis of Claim 115 wherein the material comprises an augmentation device wherein the augmentation device comprises a flexible solid that acts to increase the overall volume of material within the disc and thereby prevents a loss in height of the disc.

127. A method of inserting a membrane into an intervertebral disc comprising:
providing a membrane on an insertion device;
inserting the insertion device into the intervertebral disc; and
deploying the membrane within the intervertebral disc.

128. The method of Claim 127 further comprising affixing the membrane to tissue in or surrounding the intervertebral disc.

129. The method of Claim 127 further comprising deploying the membrane between the nucleus pulposus and the annulus fibrosis of the intervertebral disc.

130. The method of Claim 127 further comprising expanding the membrane to an expanded state.

131. The method of Claim 127 further comprising removing the insertion device from the intervertebral disc.

132. The method of Claim 127 further comprising inserting the insertion device into the intervertebral disc at a point located a distance away from a defect in the annular fibrosis of the intervertebral disc and advancing the membrane across the defect.

133. The method of Claim 127 further comprising providing a frame on which the membrane is mounted.

134. The method of Claim 127 further comprising providing a frame including an alloy of nickel and titanium.

135. The method of Claim 127 further comprising providing a frame including a longitudinal strut and a plurality of radial elements.

136. The method of Claim 127 further comprising providing a frame with a first end and a second end that extend at oblique angles relative to a longitudinal axis of the frame.

137. The prosthesis of Claim 102 for reinforcing a annulus fibrosis of a intervertebral disc, said annulus fibrosis defining an outer periphery of said disc, said prosthesis comprising a barrier having:

a length extending between a proximal end and a distal end;

a front surface perpendicular to and extending along said length, said front surface having a concave shape along at least a portion of said length; and

a back surface having a convex shape extending along at least a portion of said length said barrier being implanted within said disc such that said length extends along at least a portion of an inner circumference of said annulus fibrosis such that said front surface faces the interior of said disc and said back surface faces the outer periphery of said disc.

138. A method of positioning a dynamically stable implant within an implantation site, said implantation site comprising a first region having a tight and/or changing curvature bordered by a second region or regions having minimal or constant curvature, said method involving the steps of:

placing a relatively flexible region of said implant within said first region; and

placing a relatively stiff or rigid region of said implant within said second region.

139. The method of Claim 138 wherein said implantation site is the interior of the intervertebral disc and said implant is a barrier for preventing the migration of materials from within the disc toward the periphery of the disc.

140. The method of Claim 139 wherein said first implantation region is the annulus fibrosis and said second implantation region is a vertebral endplate or endplate cartilage.

141. The method of claim 139 wherein said first implantation region is the posterior lateral corner of the annulus fibrosis and said second region is the posterior or lateral annulus fibrosis.

142. A dissecting device for creating a path through the interior of the intervertebral disc, the disc comprising a multi-layered annulus fibrosis surrounding a softer, central nuclueus pulposus, the device comprising:

a generally flexible member having a length defining a distance between a proximal and a distal end, wherein the distal end is adapted to dissect through the interior of said disc; and

at least one flexible wing located at or near the distal end of said member, said wing extending from said member in a direction substantially perpendicular to the length of said member.

143. The dissecting device of Claim 141wherein said distal end is stiff enough to dissect a path either between two layers of the annulus or through the nucleus pulposus, but flexible enough to be unable to penetrate through layers of the annulus, and said at least one wing is sharpened such that it can sever attachments between the annulus fibrosis or nucleus pulposus and the vertebral endplates.

144. The dissecting device of Claim 141 further comprising a cannula having a length and a diameter, said diameter being less than the height of said disc, wherein said member and said at least one wing are adapted to be inserted into the disc through said cannula, said cannula acting to collapse said at least one wing such that when said wing is expelled from said cannula into said disc it expands to contact said endplates.

145. An intervertebral prosthesis implantation kit comprising:

a prosthesis comprises a barrier; and

a delivery device that delivers the prosthesis into an intervertebral disc.

146. The implantation kit of Claim 145 wherein the prosthesis comprises a frame and a membrane.

147. The implantation kit of Claim 145 further comprising a membrane that covers at least a portion of the frame.

148. The implantation kit of Claim 145 wherein the prosthesis comprises at least one control filament.

149. The implantation kit of Claim 145 wherein the prosthesis comprises a fixation device.

150. The implantation kit of Claim 145 wherein the delivery device comprises an advancer that inserts the prosthesis within an intervertebral disc.

151. The implantation kit of Claim 145 wherein the delivery device further comprises a thermal device.

152. The implantation kit of Claim 145 wherein the delivery device further comprises an implant guide.

153. The implantation kit of Claim 145 further comprising a predissecting tool having a size corresponding to a size of the prosthesis.

154. The prosthesis of Claim 88 wherein the prosthesis has concavity such that upon implantation into the disc the concavity is directed toward the interior of the disc.

155. The prosthesis of Claim 88 wherein the barrier comprises a frame that elastically changes from a compressed state to an expanded state upon insertion into the disc.

156. The prosthesis of Claim 88 wherein the barrier further comprising a plurality of pores, the pores having an average size in a range from $0.05mm^2$ and $0.75mm^2$.

157. The prosthesis of Claim 88 wherein the barrier comprises a frame having a thickness in a range between 0.1mm and 0.6mm.

158. The prosthesis of Claim 88 wherein the barrier comprises a frame that is constructed from a material selected from a group consisting of an alloy of nickel and titanium, stainless steel, cobalt chrome, titanium, polyethylene, and silicone rubber.

159. The prosthesis of Claim 88 wherein the membrane has a thickness in a range between 0.025mm and 2.5mm.

160. The prosthesis of Claim 88 wherein the membrane is constructed from a material selected from a group consisting of synthetic polyamide, synthetic polyester, polyethylene, collagen, PTFE, and e-PTFE.

161. The prosthesis of Claim 88 wherein the prosthesis has at least one flexible region that can extend along a posterior annulus, at least one flexible region being flexible against bending about an axis parallel to the posterior annulus, and at least one stiff region extending toward at least one

vertebral end plate, the stiff region being resistant to bending about said axis relative to the flexible region.

162. The prosthesis of Claim 88 wherein the prosthesis has a first stiff region along the posterior annulus and a second stiff region along a lateral side of the annulus, the stiff regions being resistant to bending about an axis parallel to a sagittal axis; the first and second regions are separated by a flexible region that is flexible to bending about said axis.

163. The prosthesis of Claim 2 wherein the frame expands elastically from a compressed state to an expanded state upon insertion into the disc.

164. The prosthesis of Claim 2 further comprising a plurality of pores in the frame wherein the pores have an average size in a range from 0.05mm2 and 0.75mm^2.

165. The prosthesis of Claim 1 wherein the prosthesis has at least one flexible region along the posterior annulus, the at least one flexible region being flexible against bending about an axis parallel to the posterior annulus; and at least one stiff region extending toward at least one vertebral endplate, the stiff region being relatively resistant to bending about said axis.

166. The prosthesis of Claim 1 wherein the prosthesis has a first stiff region along the posterior annulus and a second stiff region along a lateral side of the annulus, the stiff regions being resistant to bending about an axis parallel to a sagittal axis; the first and second regions are separated by a flexible region that is flexible to bending about said axis.

167. The prosthesis of Claim 17 wherein the prosthesis has a concavity such that upon implantation into the disc the concavity is directed toward the interior of the disc.

168. The prosthesis of Claim 19 wherein the frame expands elastically from a compressed state to an expanded state upon insertion into the disc.

169. The prosthesis of Claim 19 further comprising a plurality of pores in the frame wherein the pores have an average size in a range from 0.05mm2 and 0.75mm^2.

170. The prosthesis of Claim 22 wherein the prosthesis has a concavity such that upon implantation into the disc the concavity is directed toward the interior of the disc.

171. The prosthesis of Claim 23 wherein the frame expands elastically from a compressed state to an expanded state upon insertion into the disc.

172. The prosthesis of Claim 23 further comprising a plurality of pores in the frame wherein the pores have an average size in a range from 0.05mm2 and 0.75mm^2.

173. The prosthesis of Claim 23 wherein the frame has a thickness in a range between 0.1mm and 0.6mm.

174. The prosthesis of Claim 23 wherein the frame is constructed from a material selected from a group consisting of an alloy of nickel and titanium, stainless steel, cobalt chrome, titanium, polyethylene, and silicone rubber.

175. The prosthesis of Claim 25 wherein the membrane has a thickness in a range between 0.025mm and 2.5mm.

176. The prosthesis of Claim 25 wherein the membrane is constructed from a material selected from a group consisting of synthetic polyamide, synthetic polyester, polyethylene, collagen, PTFE, and e-PTFE.

177. The prosthesis of Claim 22 wherein the prosthesis has at least one flexible region along the posterior annulus, the at least one flexible region being flexible against bending about an axis parallel to the posterior annulus; and at least one stiff region extending toward at least one vertebral endplate, the stiff region being relatively resistant to bending about said axis.

178. The prosthesis of Claim 22 wherein the prosthesis has a first stiff region along the posterior annulus and a second stiff region along a lateral side of the annulus, the stiff regions being resistant to bending about an axis parallel to a sagittal axis; the first and second regions are separated by a flexible region that is flexible to bending about said axis.

179. The prosthesis of Claim 27 wherein the prosthesis comprises a barrier that prevents migration of material toward an outer periphery of the disc.

180. The prosthesis of Claim 27 wherein the prosthesis has a concavity such that upon implantation into the disc the concavity is directed toward the interior of the disc.

181. The prosthesis of Claim 27 wherein the frame expands elastically from a compressed state to an expanded state upon insertion into the disc.

182. The prosthesis of Claim 27 further comprises a plurality of pores wherein the pores have an average size in a range from 0.05mm2 and 0.75mm^2.

183. The prosthesis of Claim 27 wherein the frame has a thickness in a range between 0.1mm and 0.6mm.

184. The prosthesis of Claim 27 wherein the frame is constructed from a material selected from a group consisting of an alloy of nickel and titanium, stainless steel, cobalt chrome, titanium, polyethylene, and silicone rubber.

185. The prosthesis of Claim 27 wherein the membrane has a thickness in a range between 0.025mm and 2.5mm.

186. The prosthesis of Claim 27 wherein the membrane is constructed from a material selected from a group consisting of synthetic polyamide, synthetic polyester, polyethylene, collagen, PTFE, and e-PTFE.

187. The prosthesis of Claim 27 wherein the prosthesis has at least one flexible region along the posterior annulus, the at least one flexible region being flexible against bending about an axis parallel to the posterior annulus; and at least one stiff region extending toward at least one vertebral endplate, the stiff region being relatively resistant to bending about said axis.

188. The prosthesis of Claim 27 wherein the prosthesis has a first stiff region along the posterior annulus and a second stiff region along a lateral side of the annulus, the stiff regions being resistant to bending about an axis parallel to a sagittal axis; the first and second regions are separated by a flexible region that is flexible to bending about said axis.

189. The prosthesis of Claim 102 further comprising a frame and a membrane.

190. The prosthesis of Claim 189 wherein the frame expands elastically from a compressed state to an expanded state upon insertion into the disc.

191. The prosthesis of Claim 189 further comprising a plurality of pores in the frame wherein the pores have an average size in a range from 0.05mm2 and 0.75mm^2.

192. The prosthesis of Claim 189 wherein the frame has a thickness in a range between 0.1mm and 0.6mm.

193. The prosthesis of Claim 189 wherein the frame is constructed from a material selected from a group consisting of an alloy of nickel and titanium, stainless steel, cobalt chrome, titanium, polyethylene, and silicone rubber.

194. The prosthesis of Claim 115 wherein the membrane has a thickness in a range between 0.025mm and 2.5mm.

195. The prosthesis of Claim 115 wherein the membrane is constructed from a material selected from a group consisting of synthetic polyamide, synthetic polyester, polyethylene, collagen, PTFE, and e-PTFE.

196. The prosthesis of Claim 102 wherein the prosthesis has at least one flexible region along the posterior annulus, the at least one flexible region being flexible against bending about an axis parallel to the posterior annulus; and at least one stiff region extending toward at least one vertebral endplate, the stiff region being relatively resistant to bending about said axis.

197. The prosthesis of Claim 102 wherein the prosthesis has a first stiff region along the posterior annulus and a second stiff region along a lateral side of the annulus, the stiff regions being resistant to bending about an axis parallel to a sagittal axis; the first and second regions are separated by a flexible region that is flexible to bending about said axis.

198. The prosthesis of Claim 102 further comprising a drug delivery membrane.

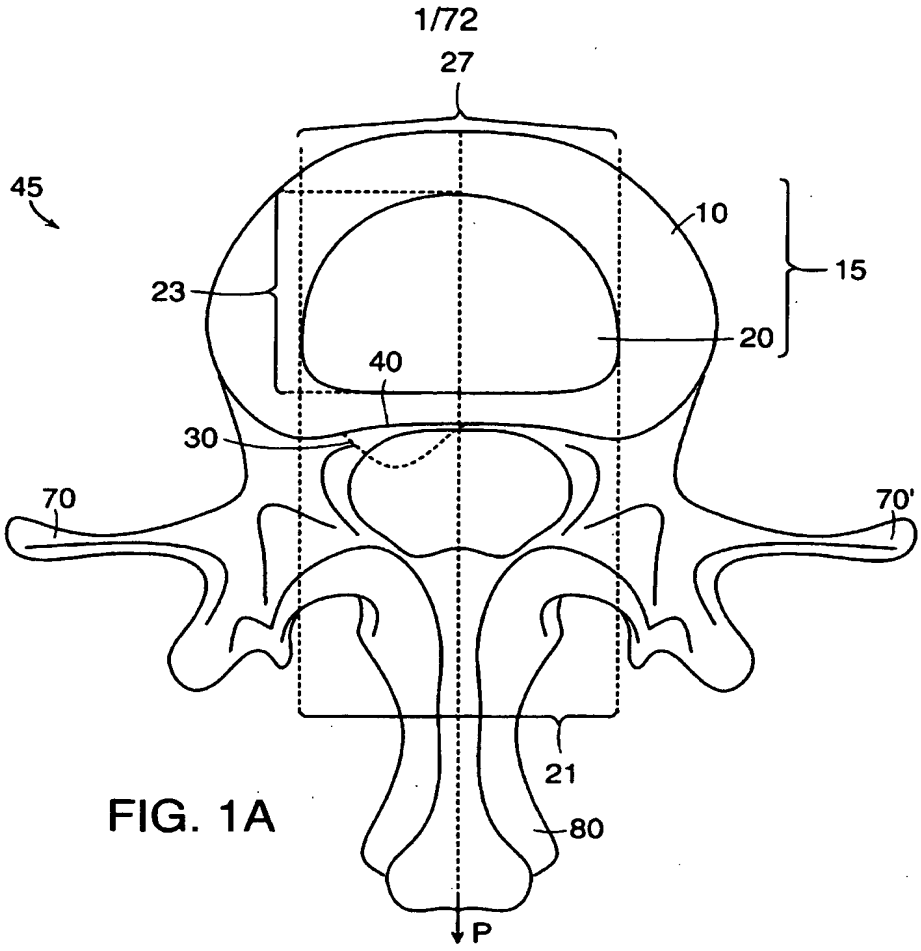
27
45
10
15
23
20
40
30
70
70'
21
80
P

FIG. 1A

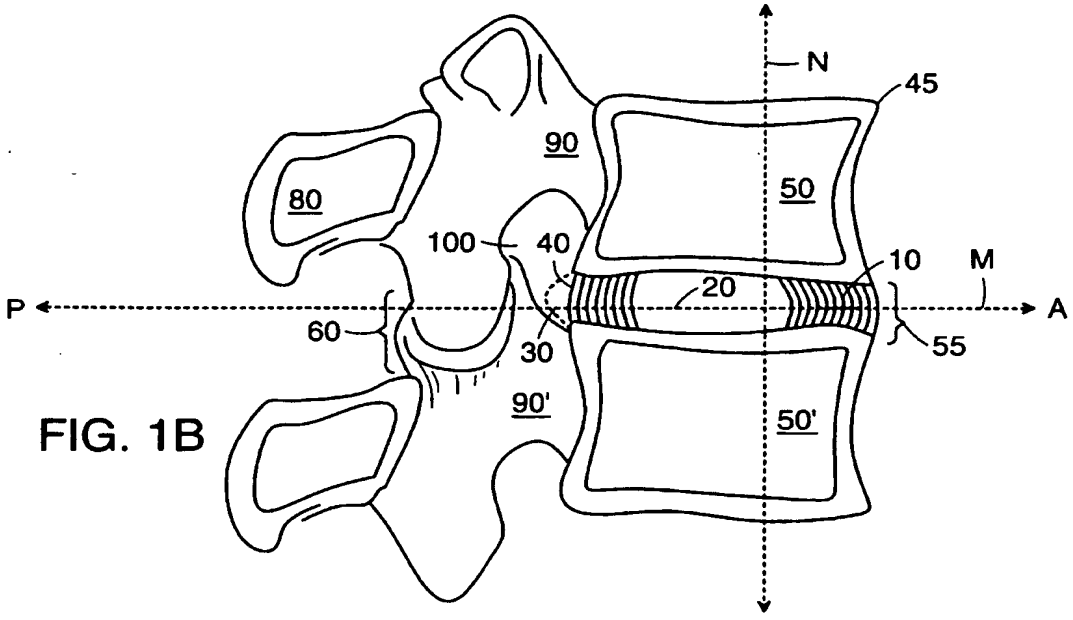
N
45
90
50
80
100
40
10
M
20
P
A
60
30
55
90'
50'

FIG. 1B

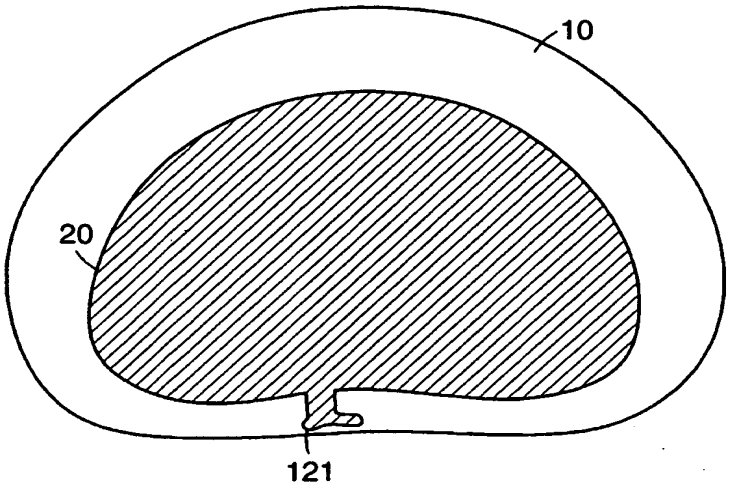

FIG. 1C

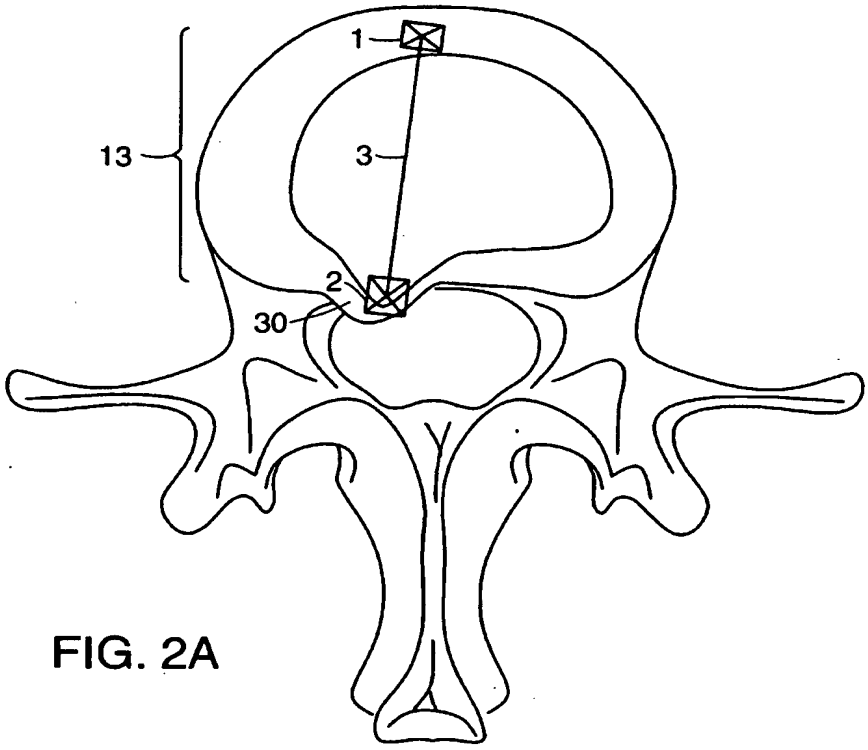

FIG. 2A

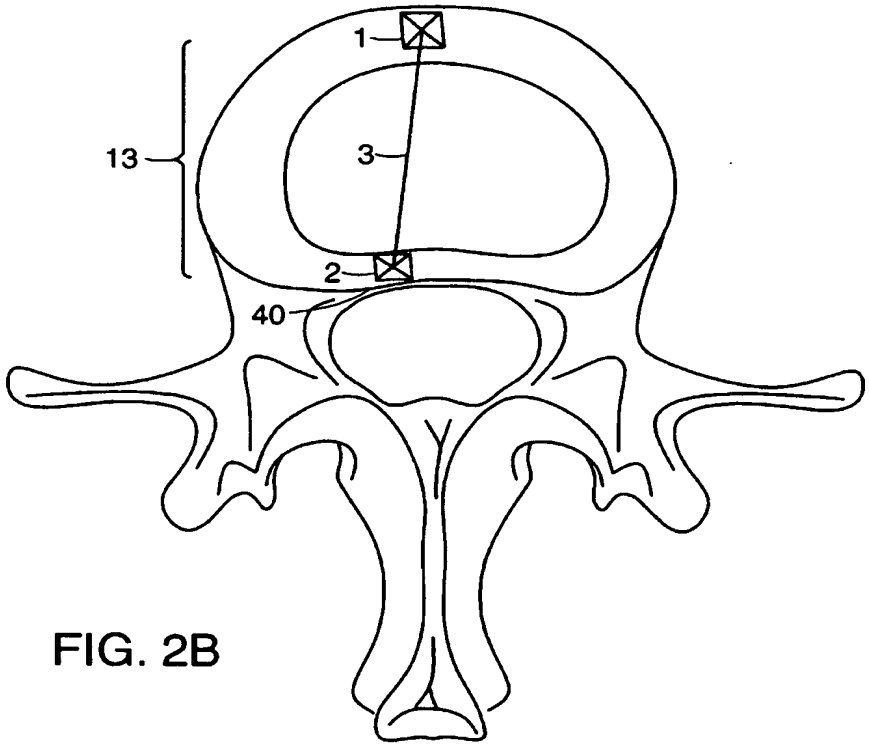

FIG. 2B

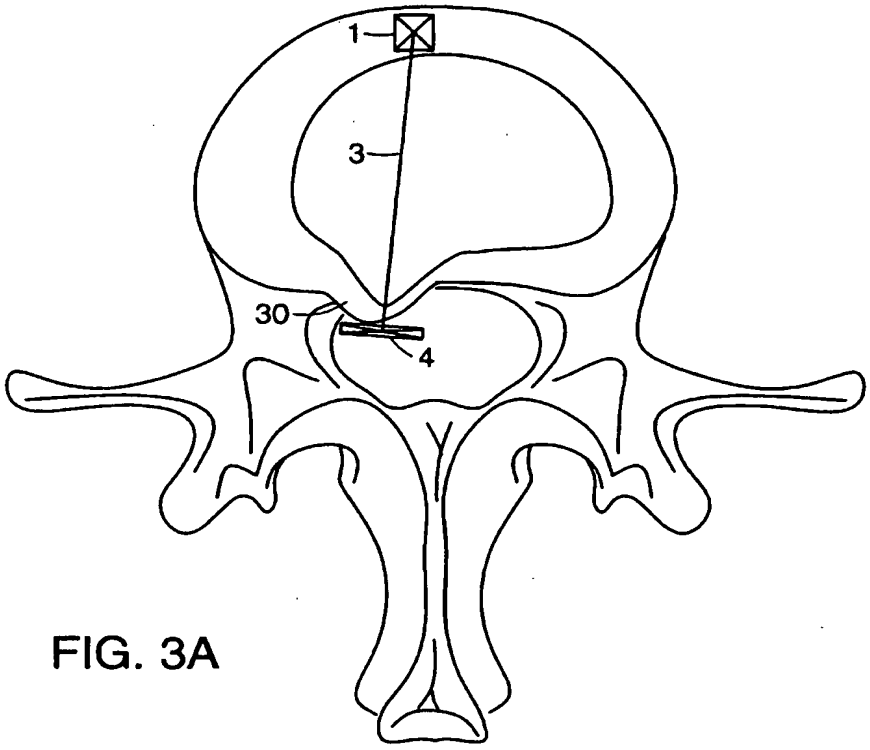

FIG. 3A

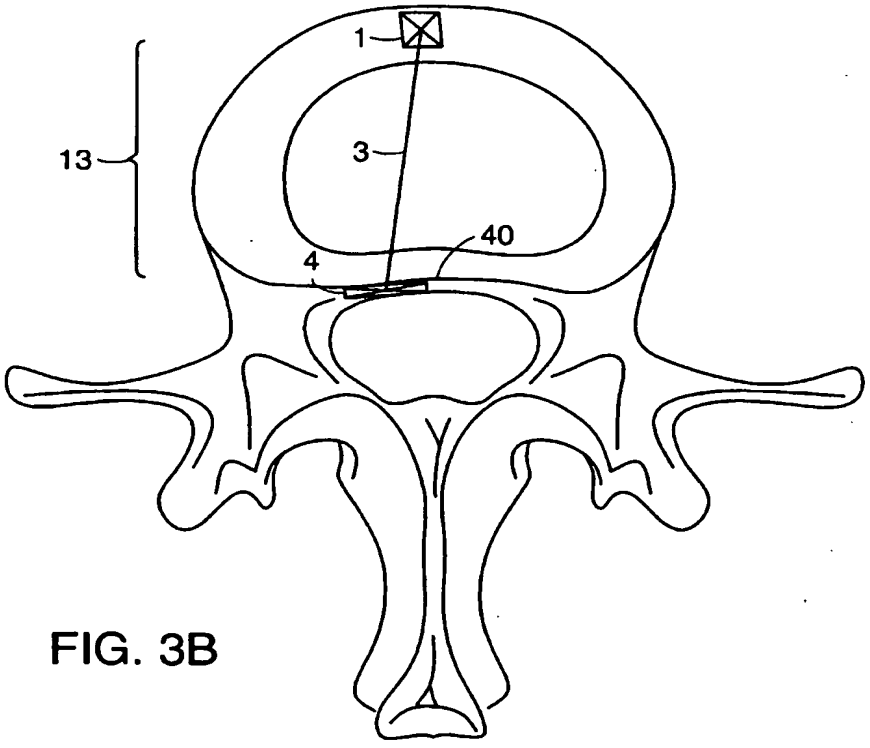

FIG. 3B

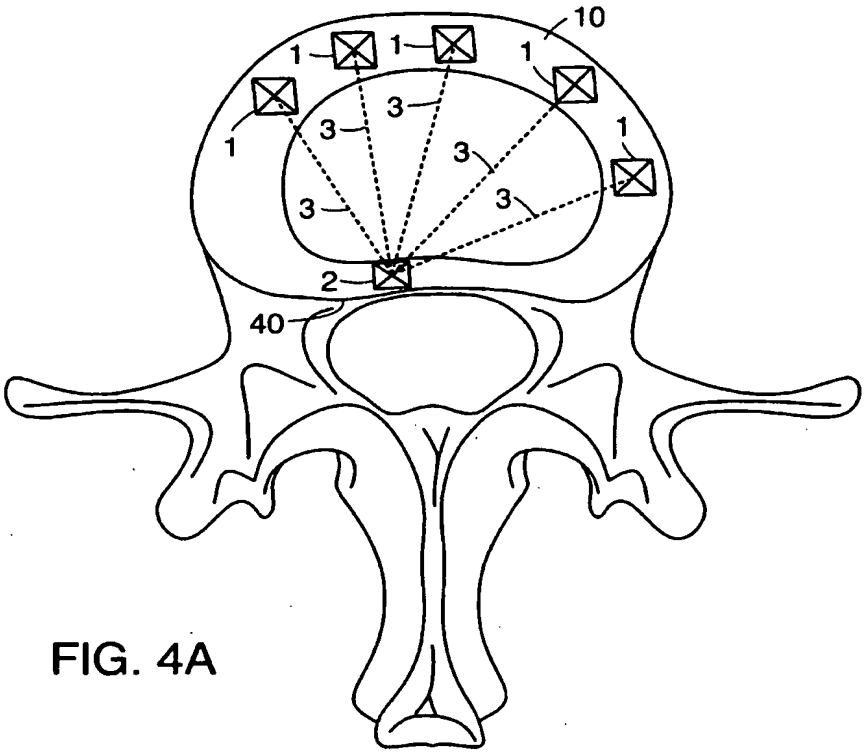

FIG. 4A

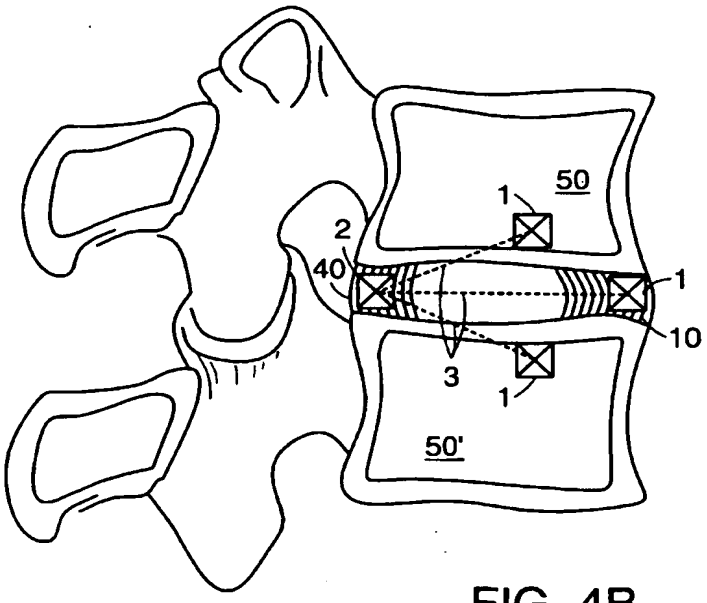

FIG. 4B

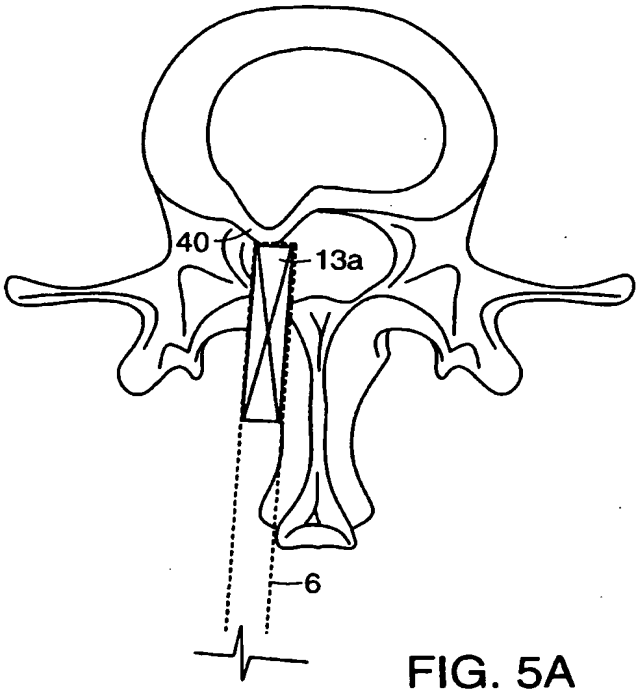

FIG. 5A

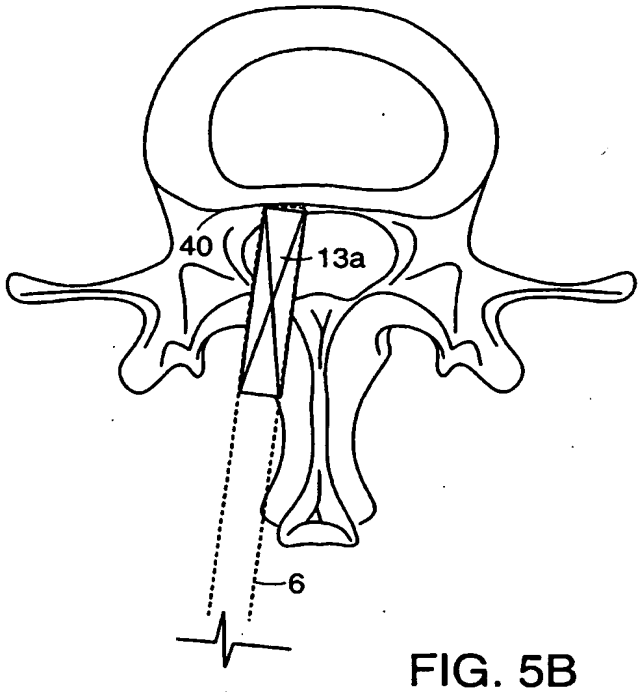

FIG. 5B

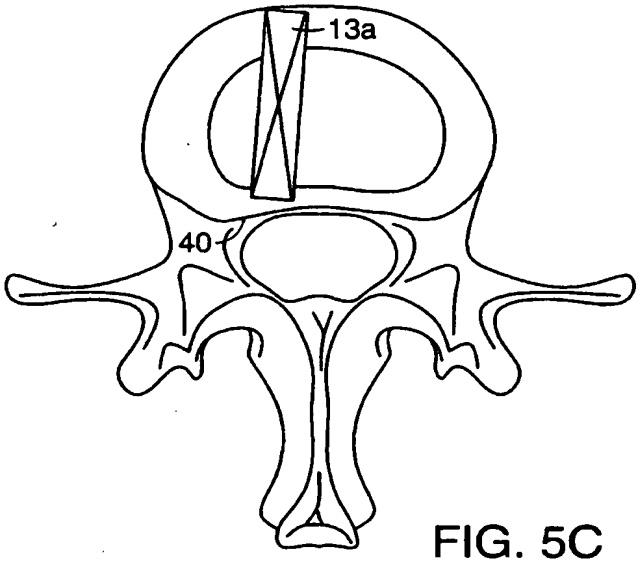

FIG. 5C

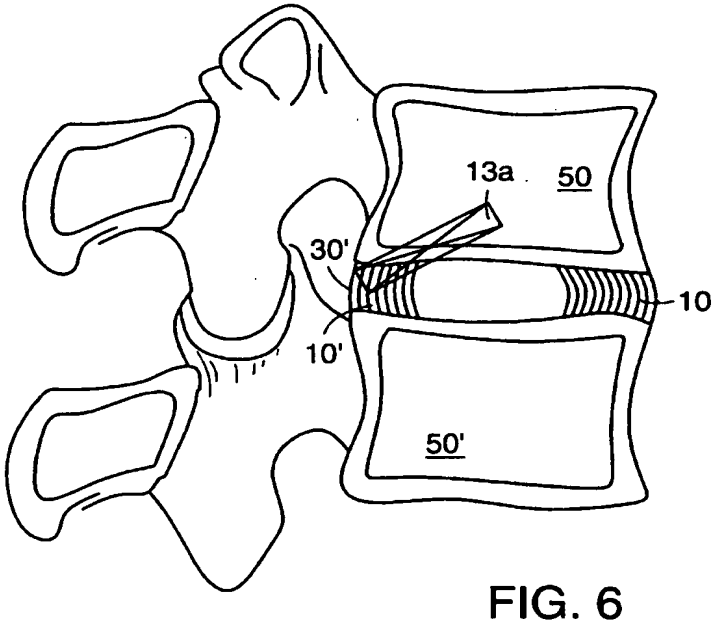

FIG. 6

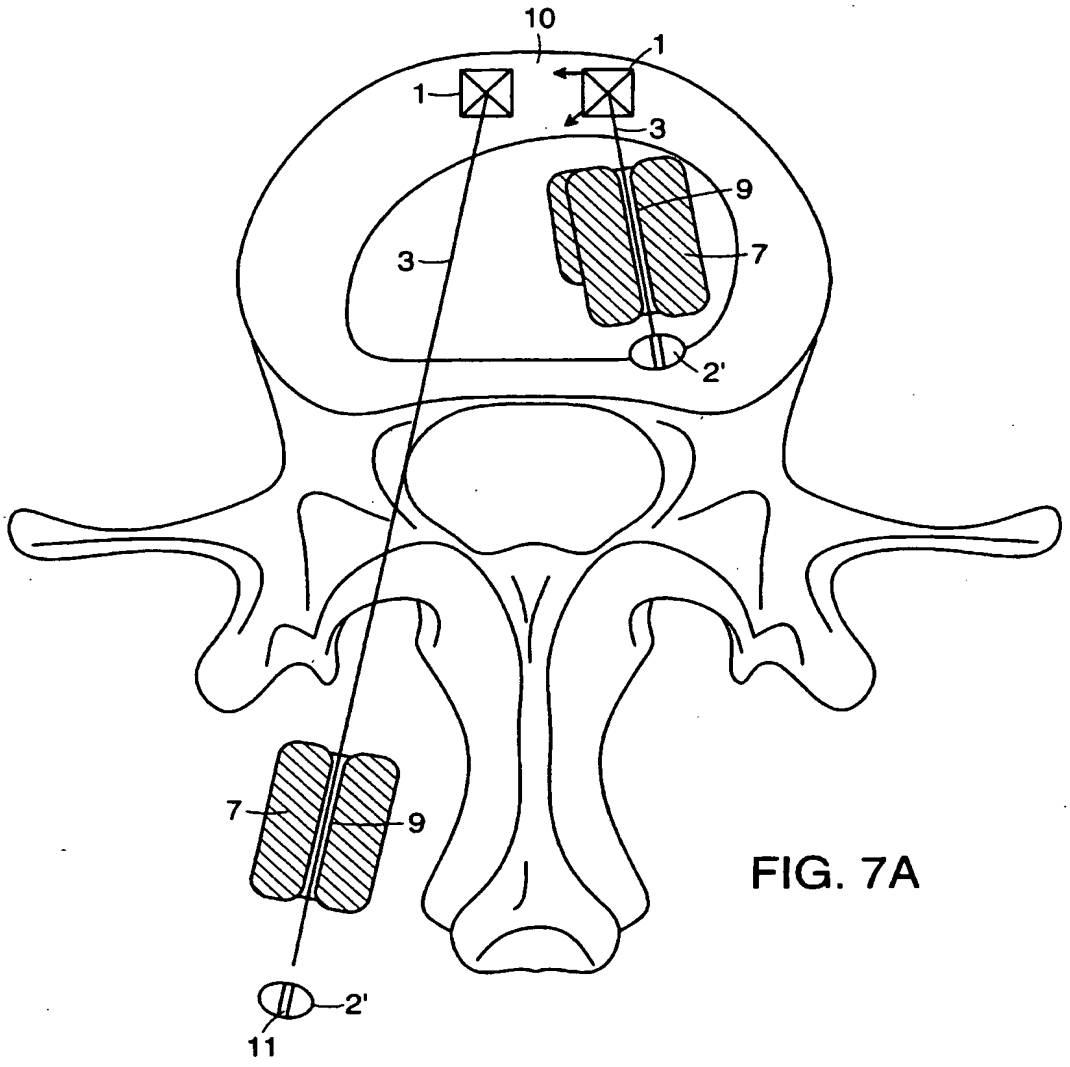

FIG. 7A

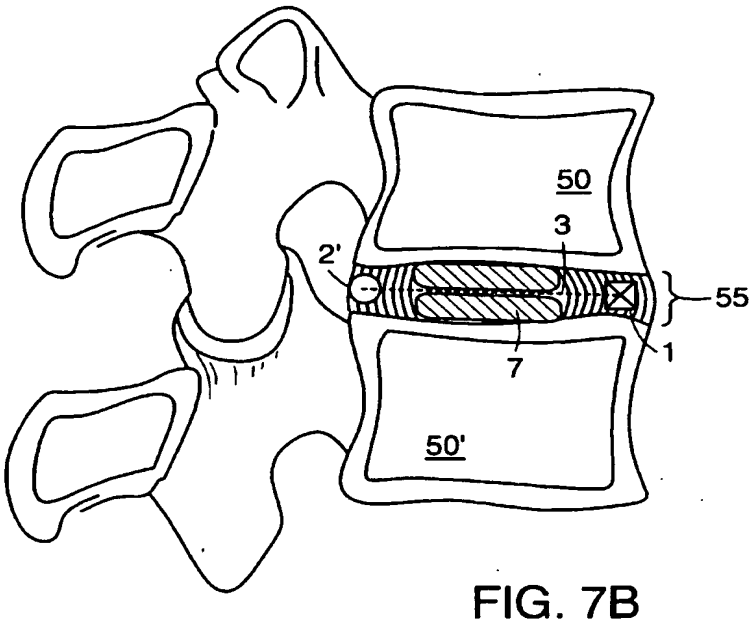

FIG. 7B

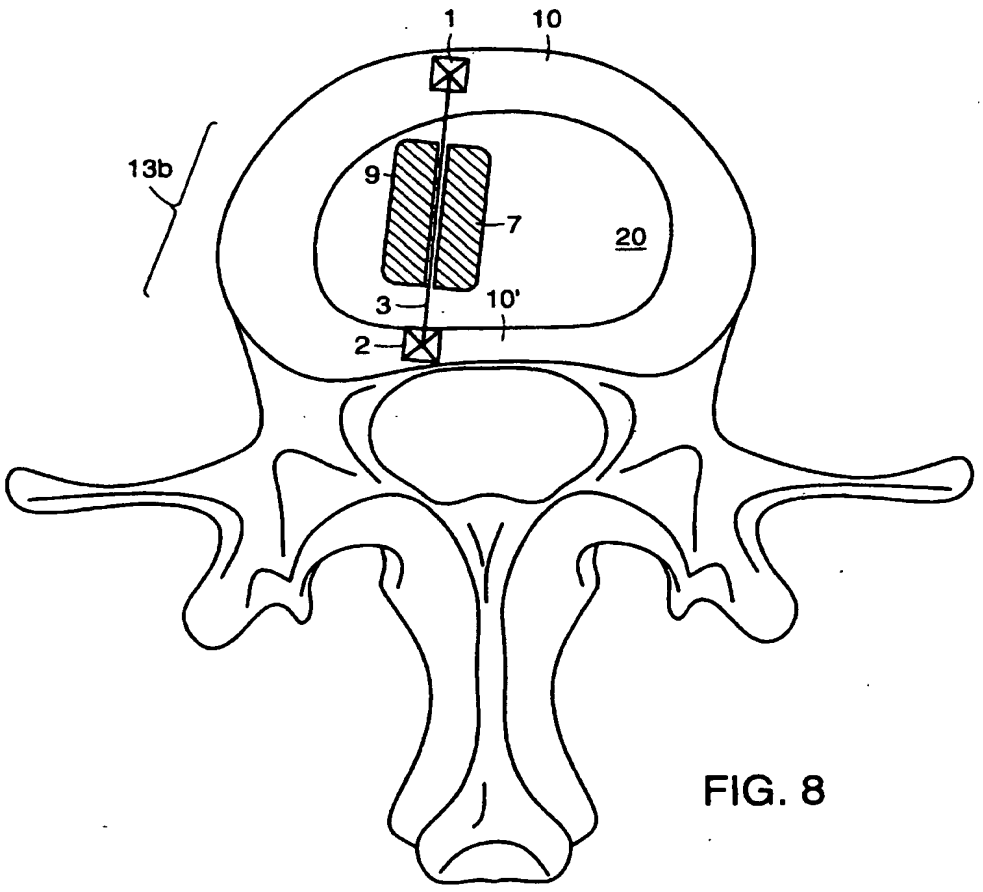

FIG. 8

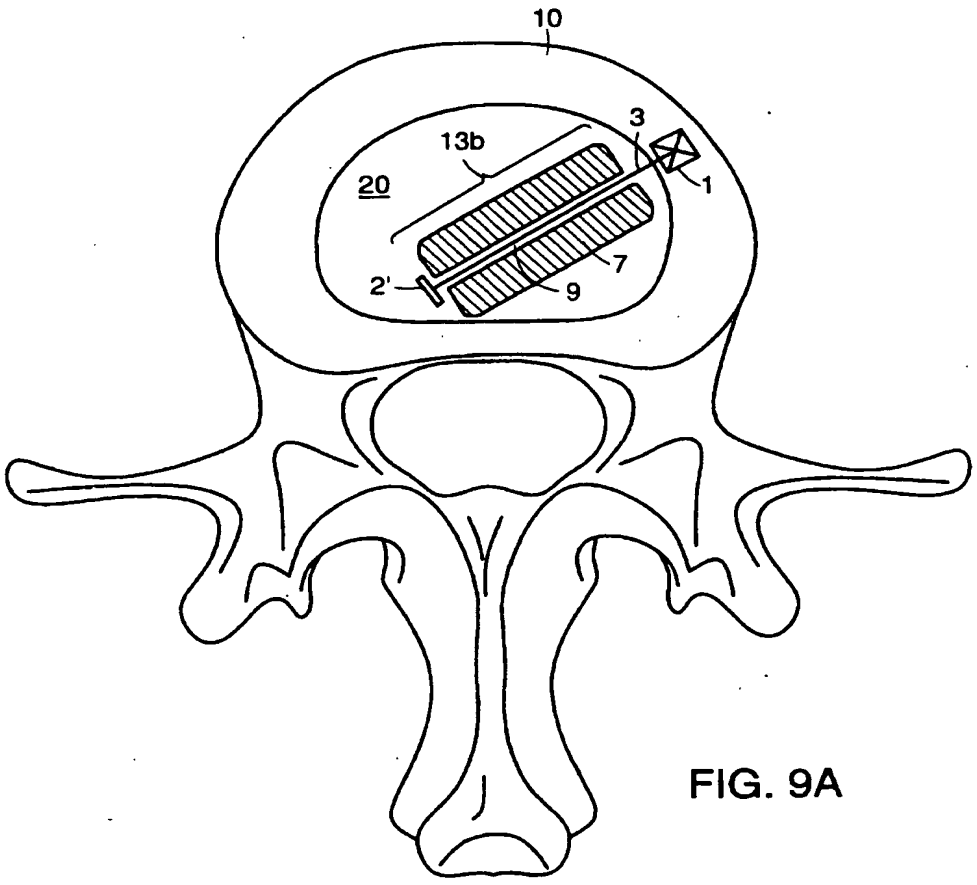

FIG. 9A

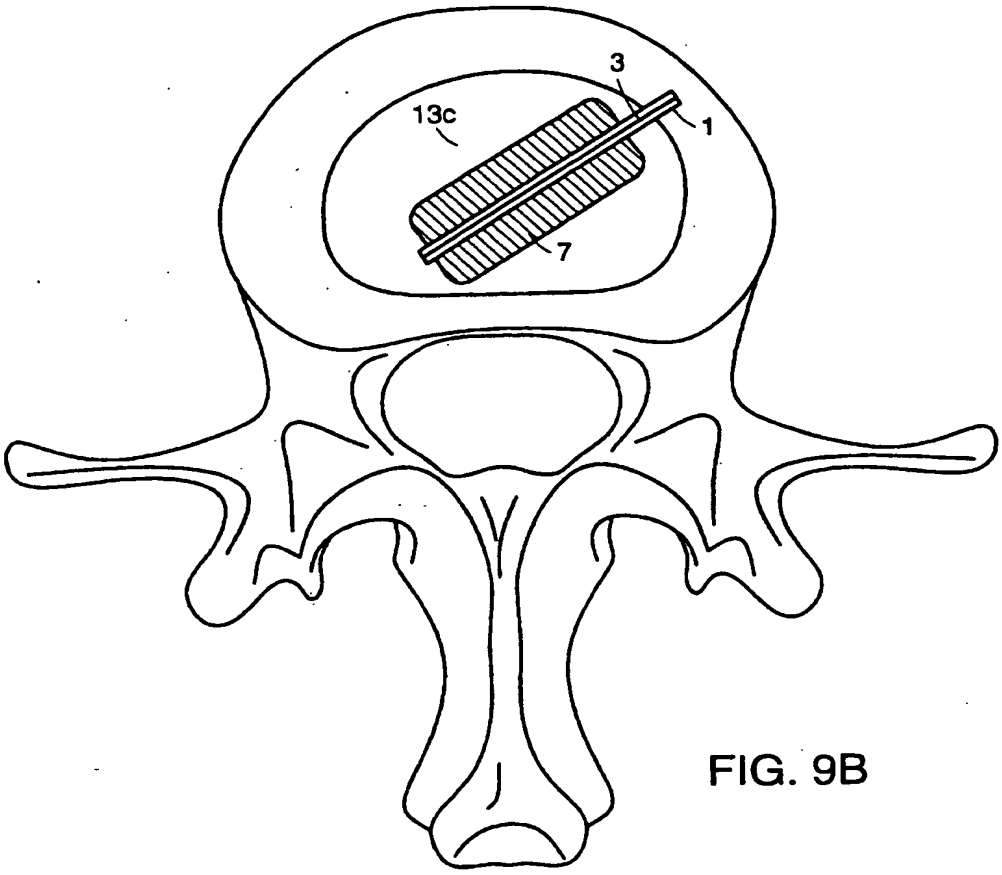

FIG. 9B

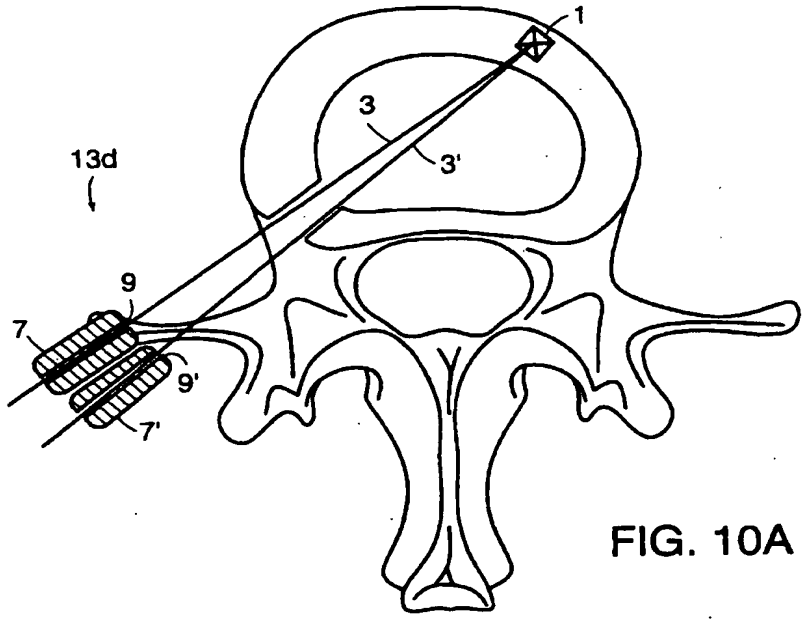

FIG. 10A

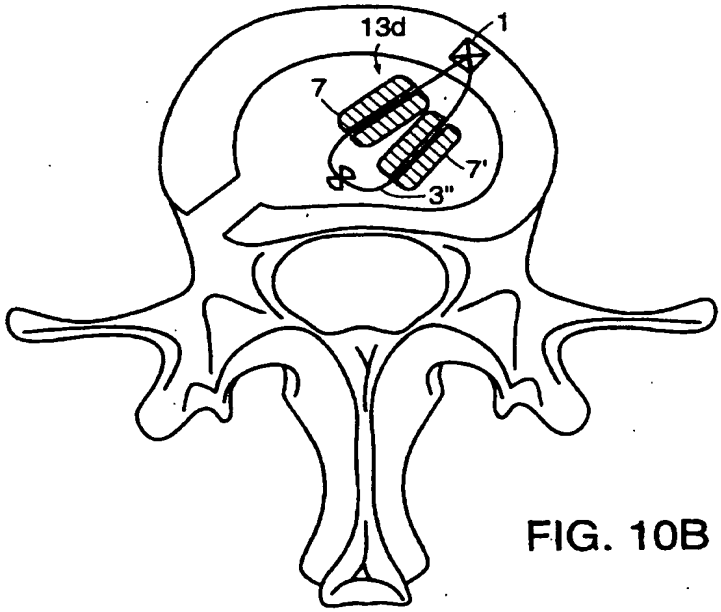

FIG. 10B

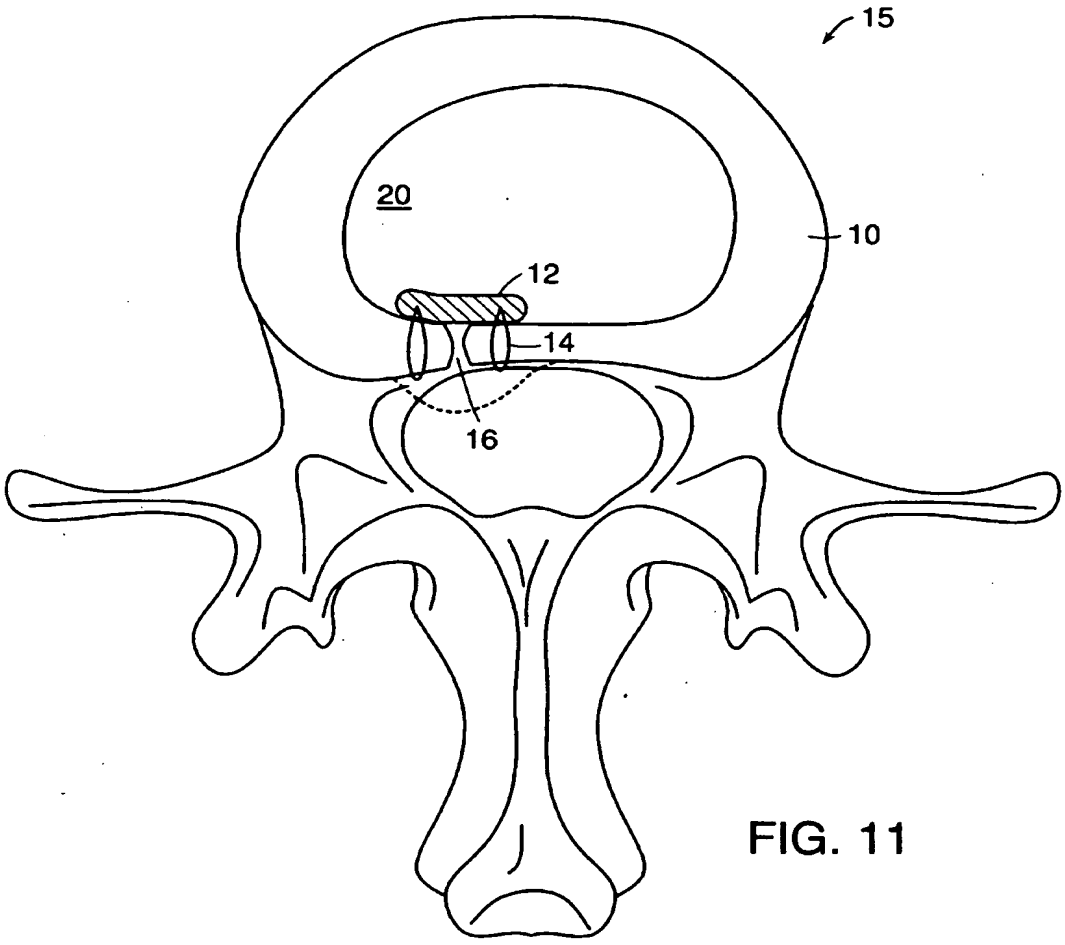

FIG. 11

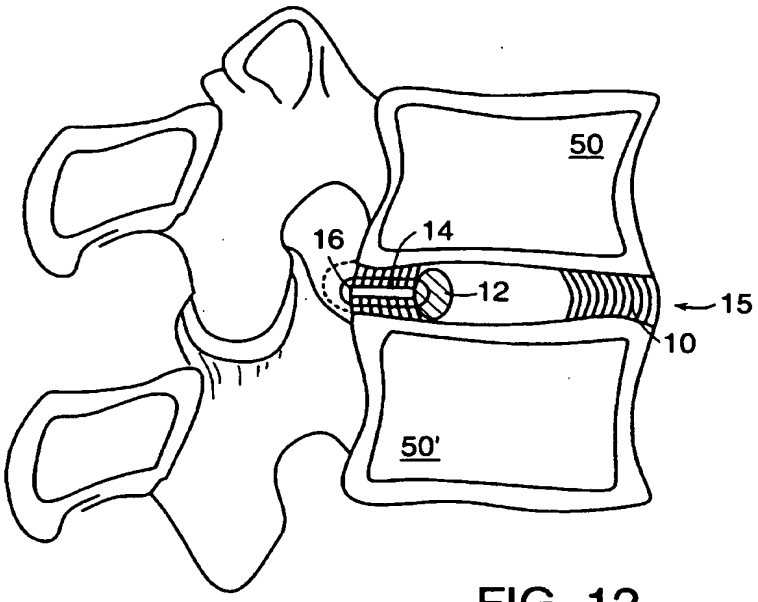

FIG. 12

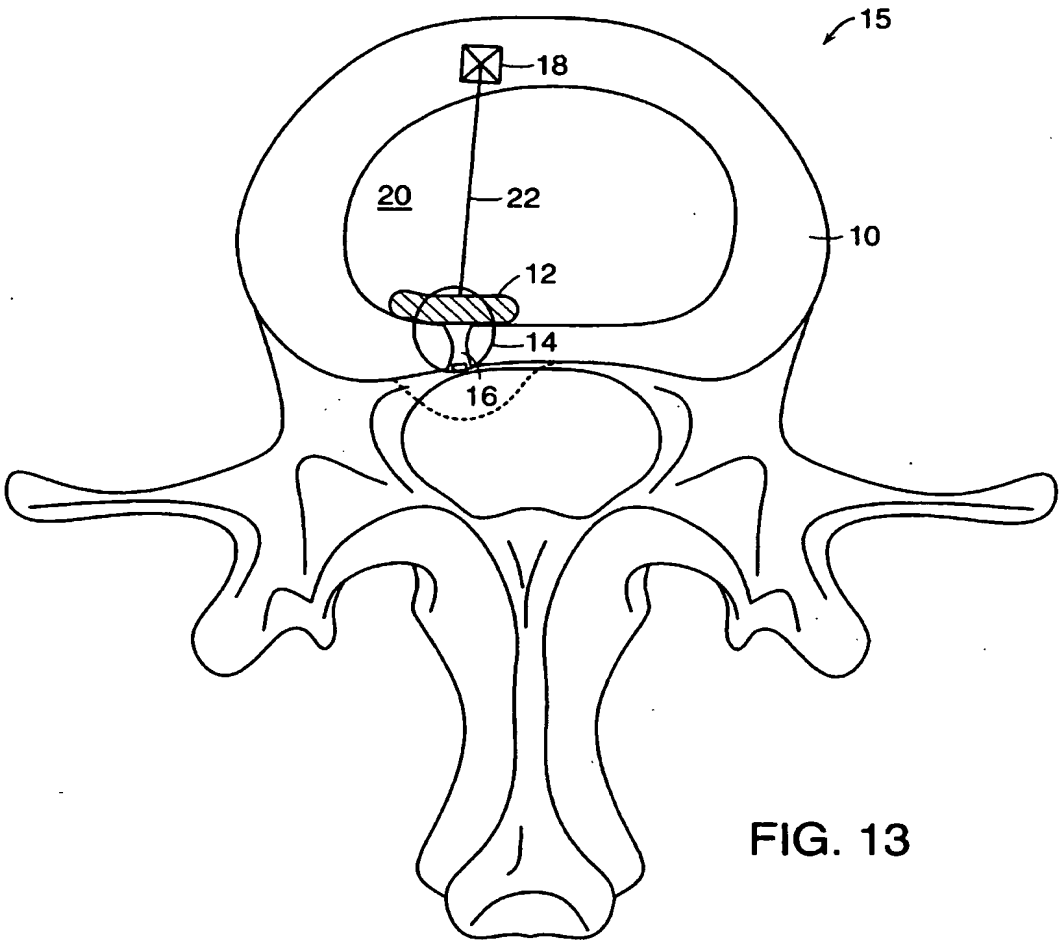

FIG. 13

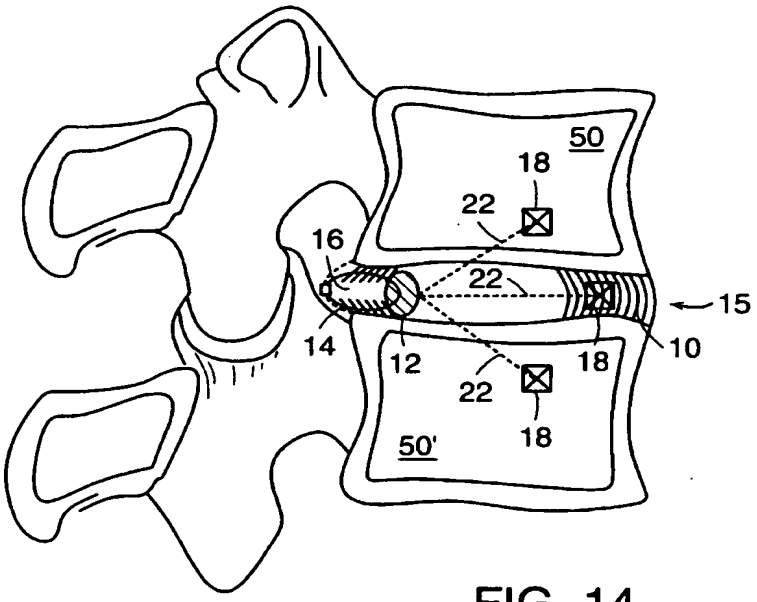

FIG. 14

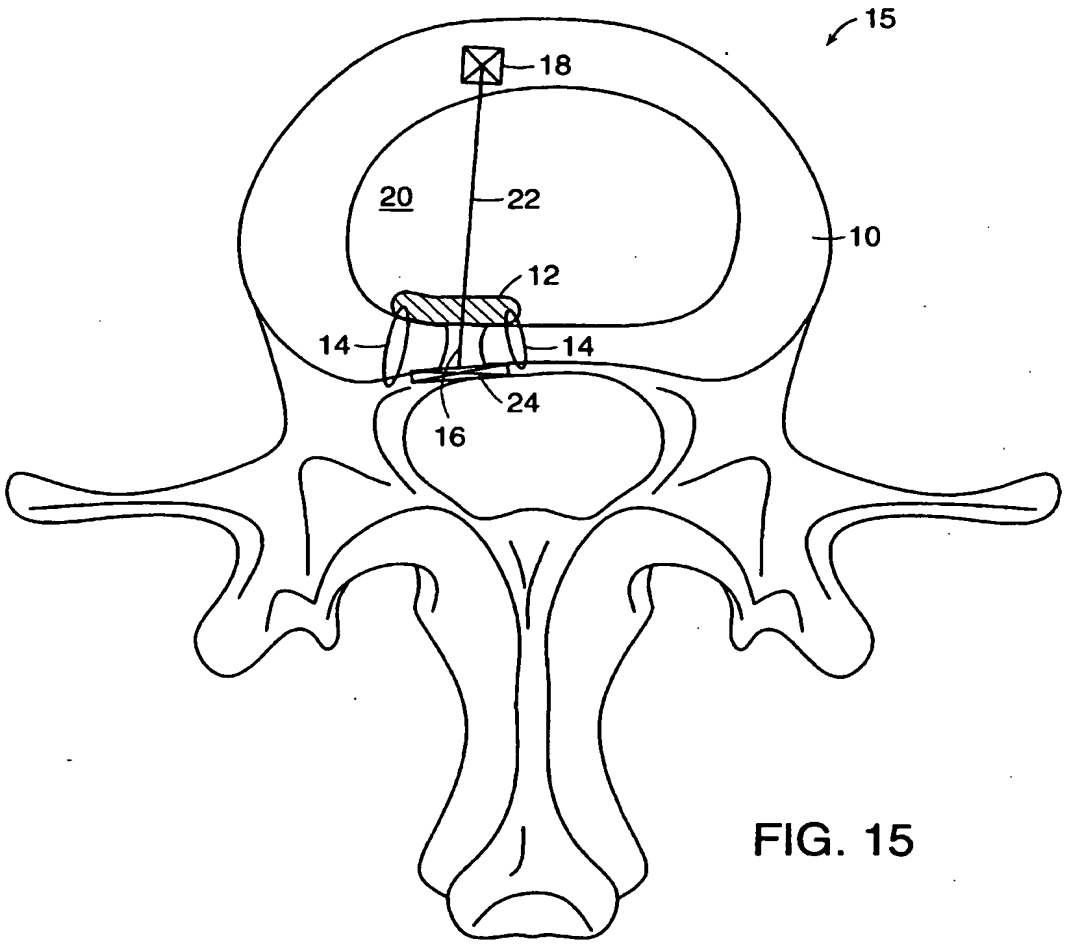

FIG. 15

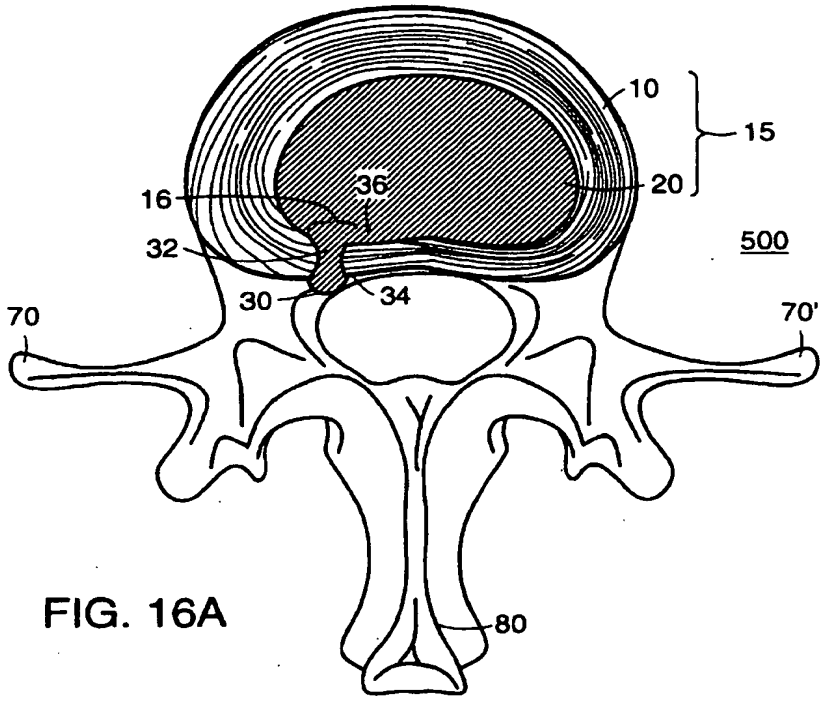

FIG. 16A

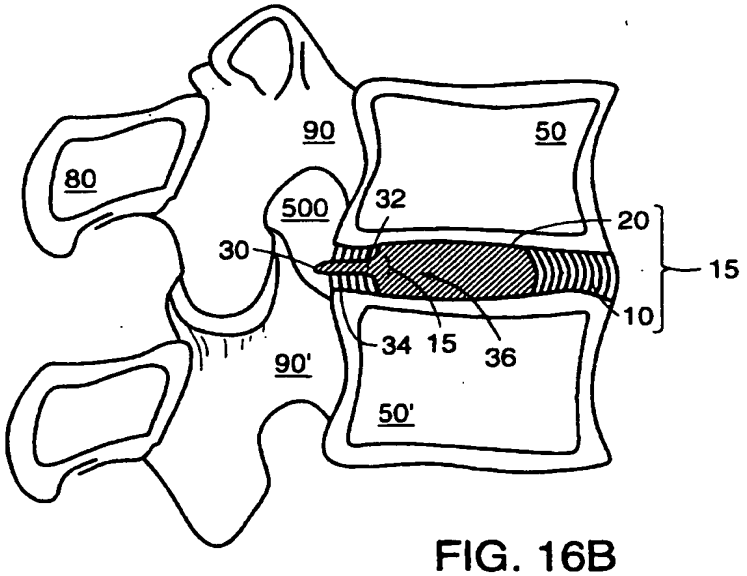

FIG. 16B

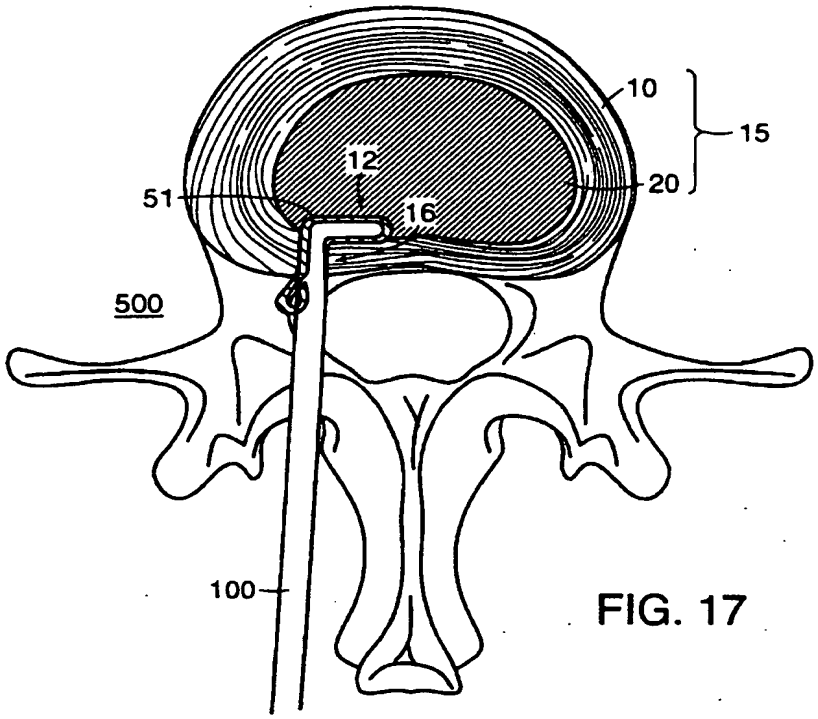

FIG. 17

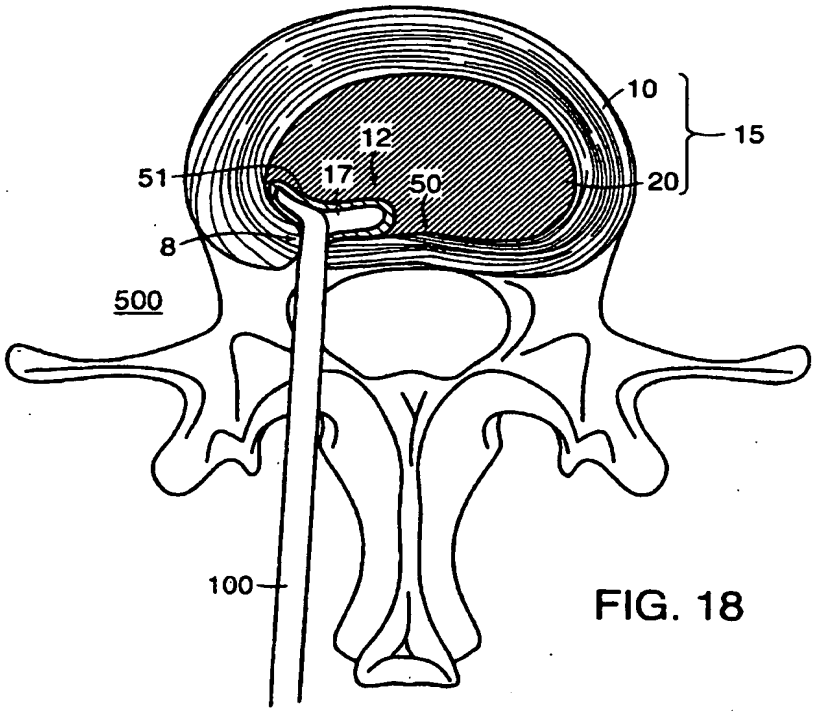

FIG. 18

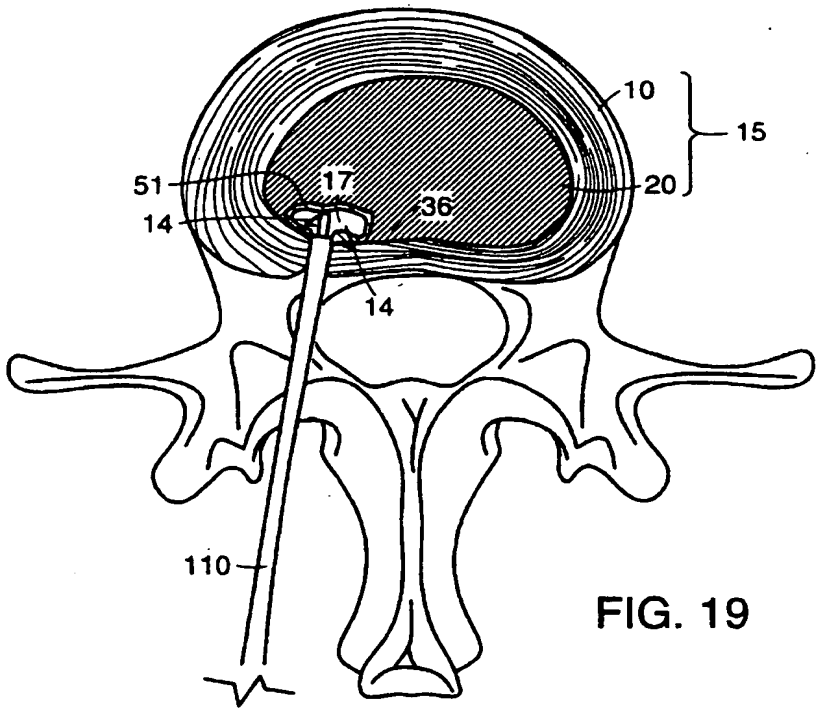

FIG. 19

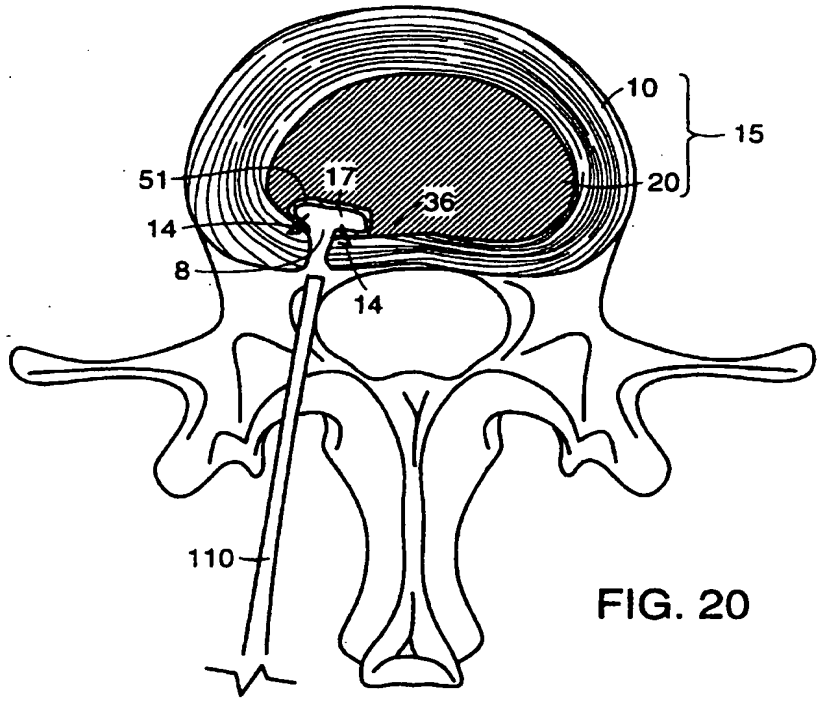

FIG. 20

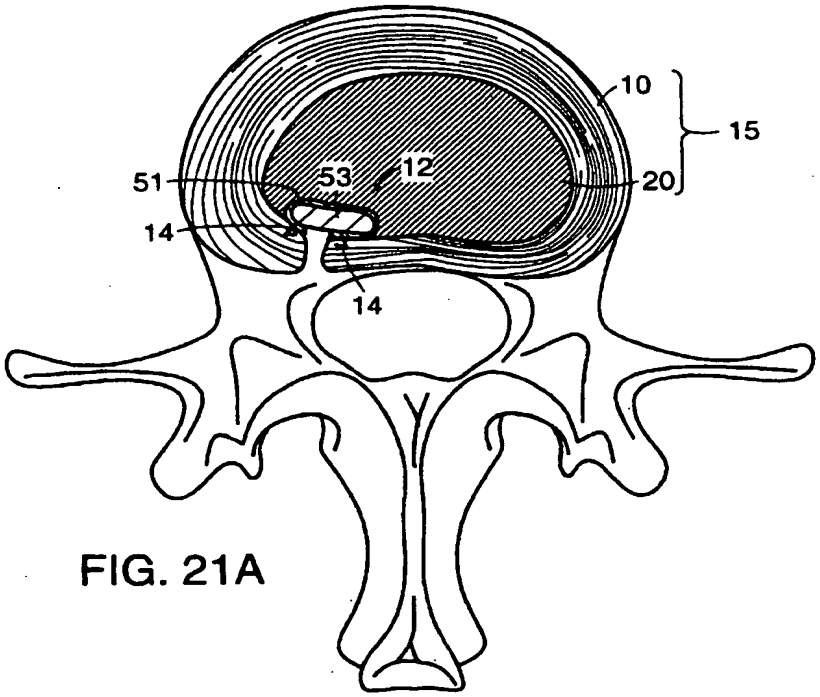

FIG. 21A

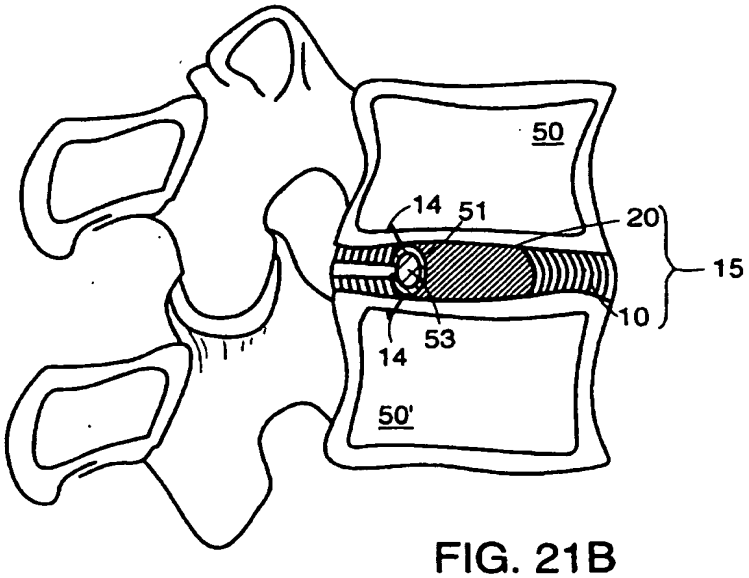

FIG. 21B

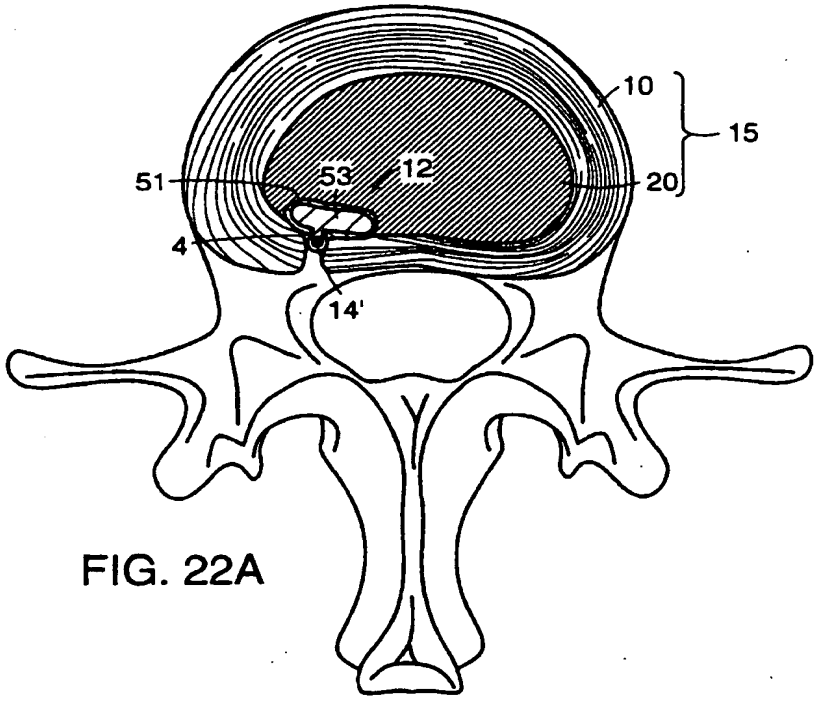

FIG. 22A

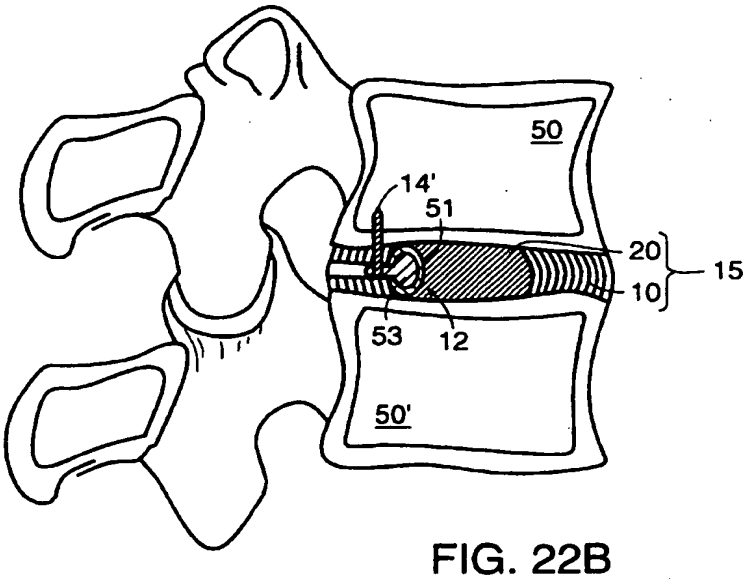

FIG. 22B

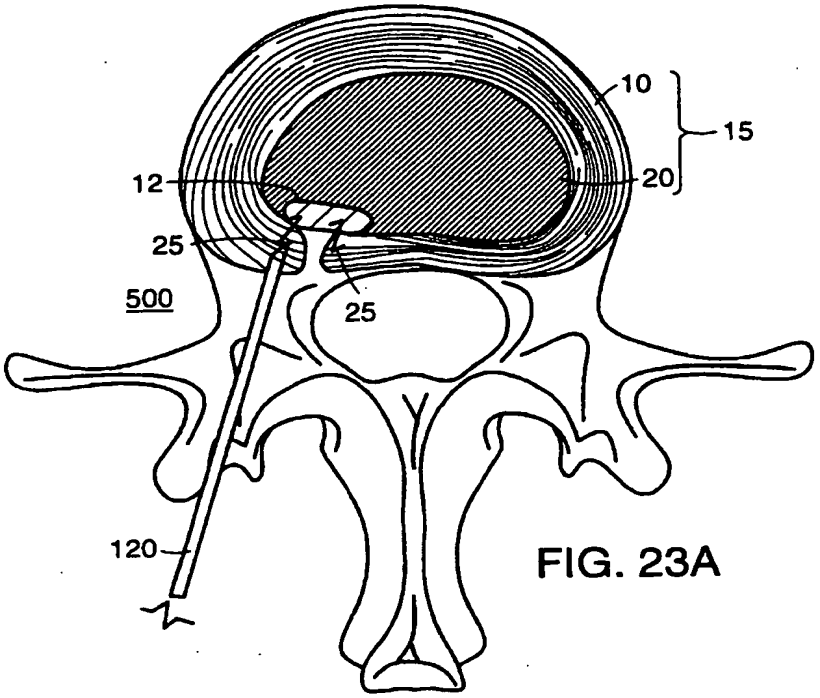

FIG. 23A

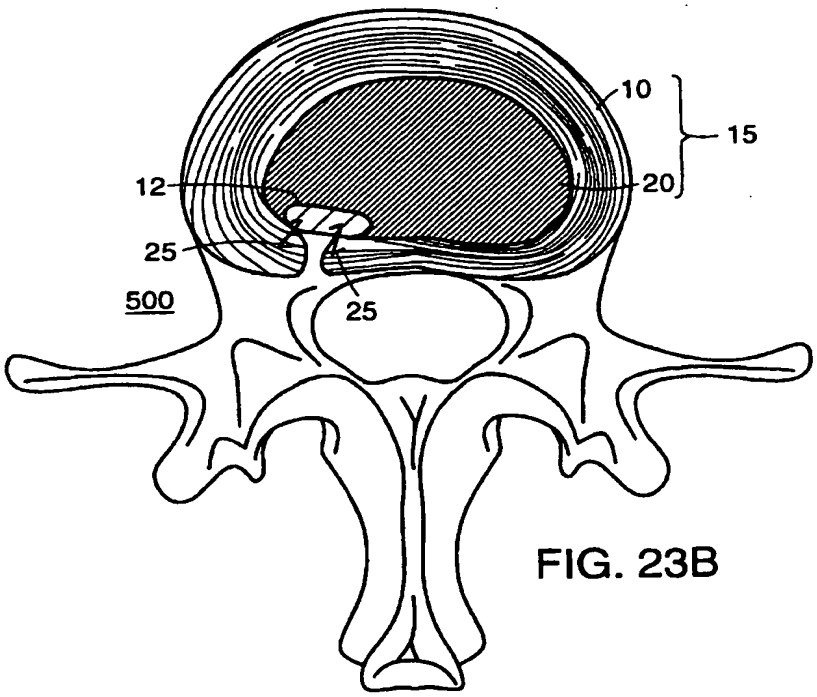

FIG. 23B

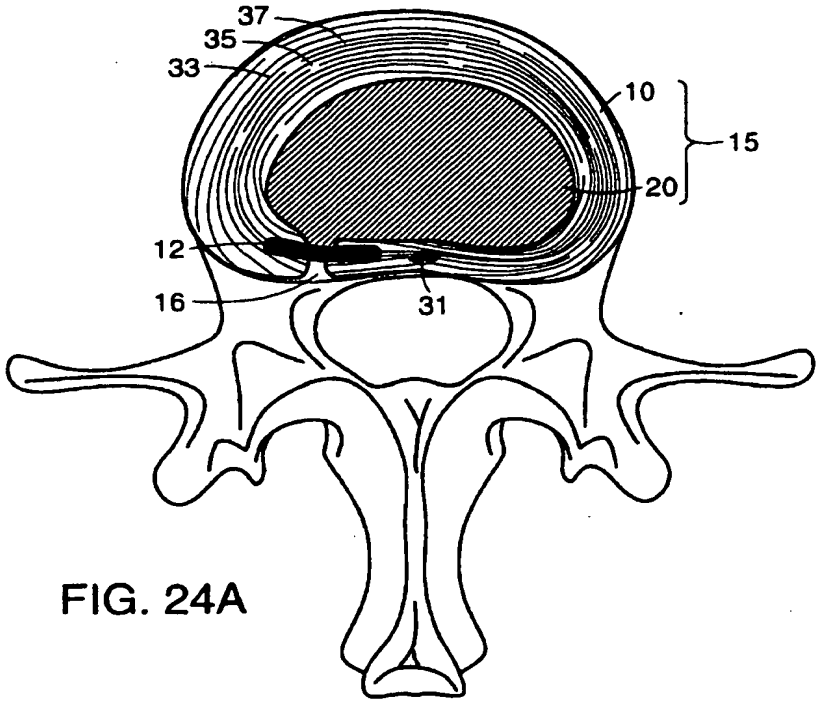

FIG. 24A

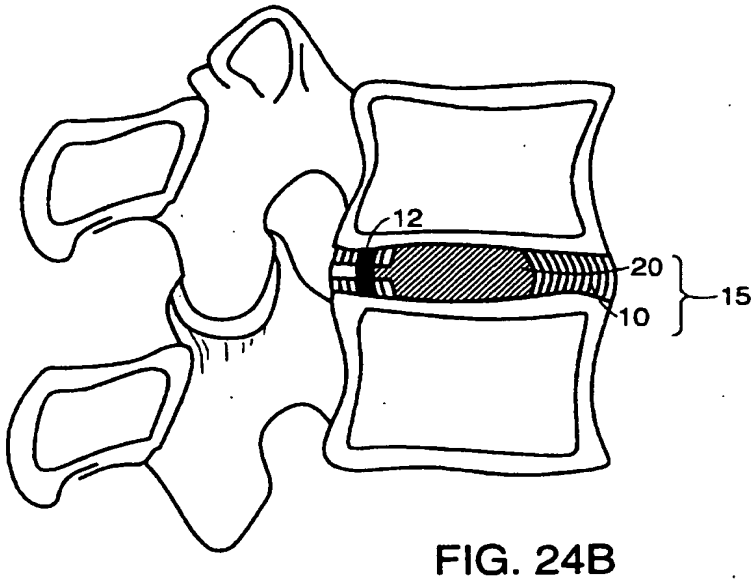

FIG. 24B

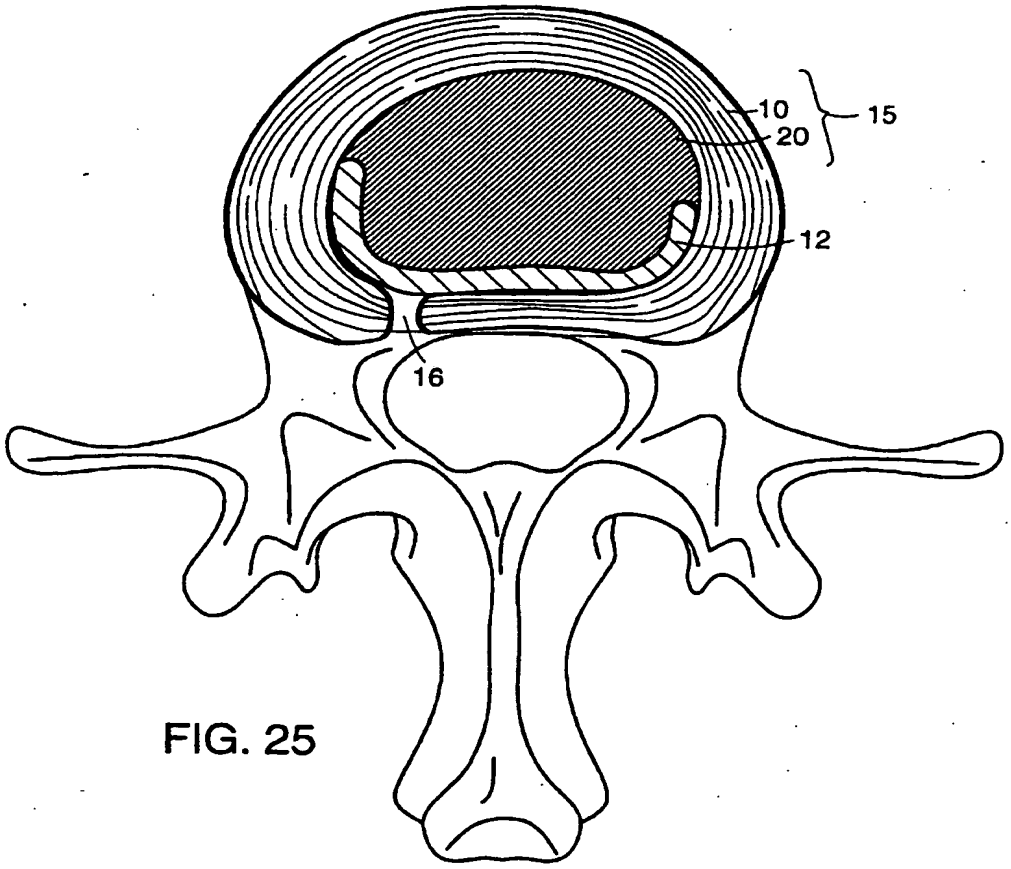

FIG. 25

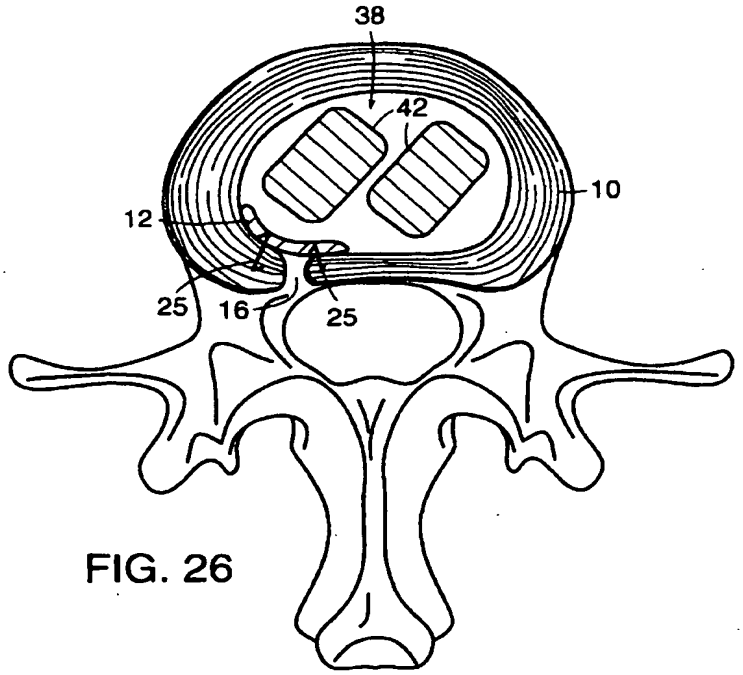

FIG. 26

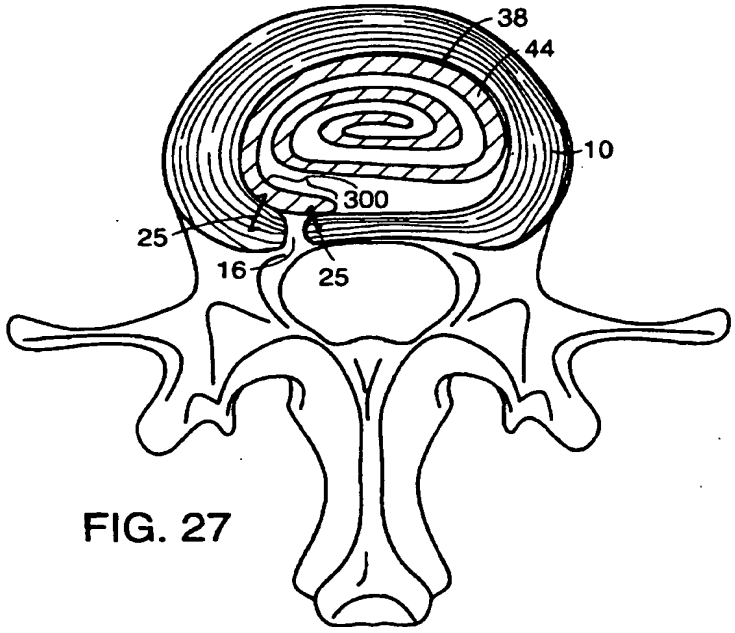

FIG. 27

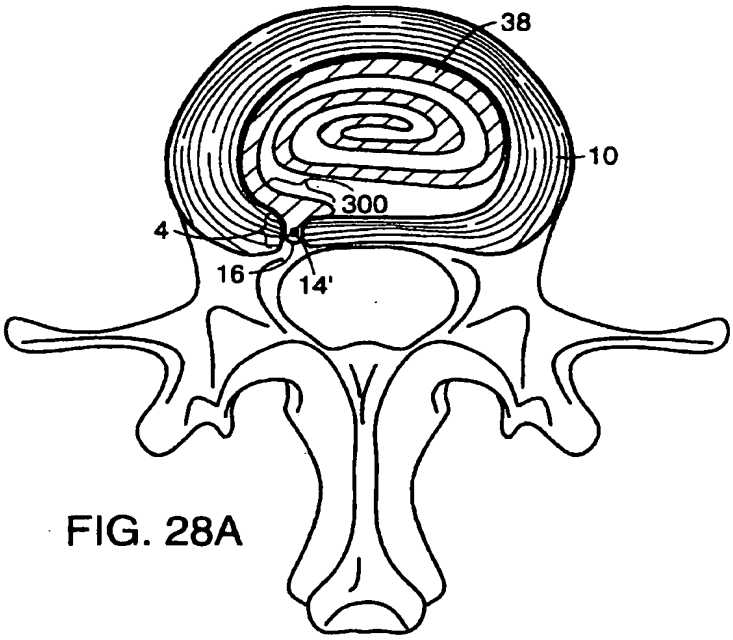

FIG. 28A

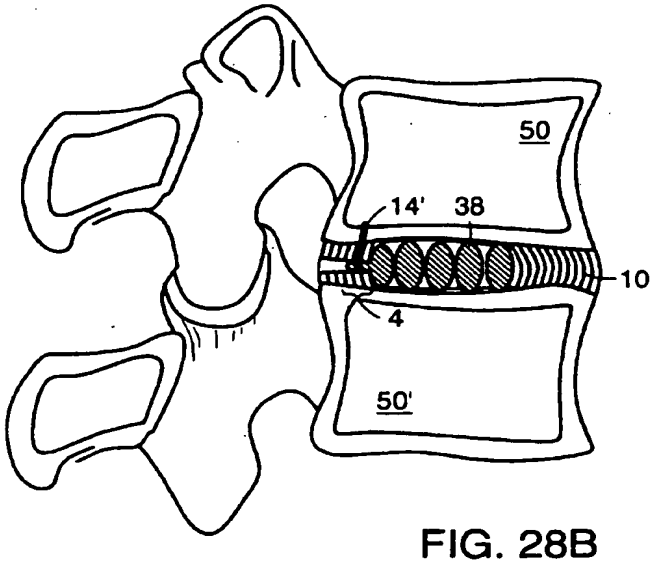

FIG. 28B

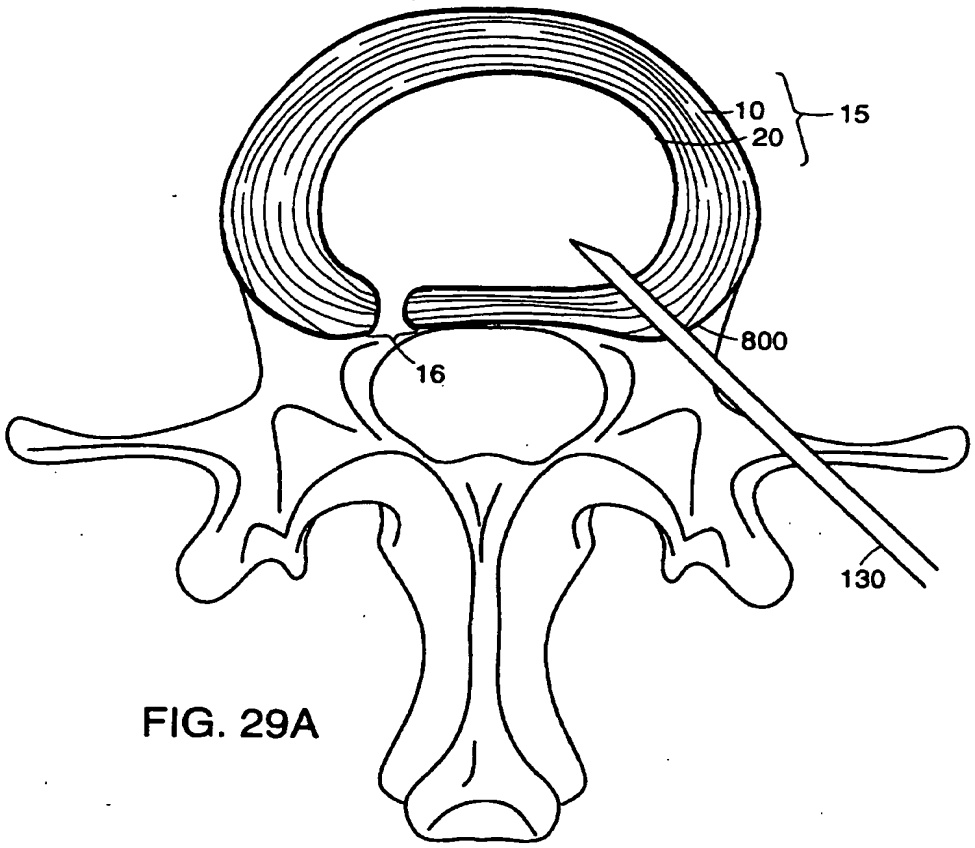

FIG. 29A

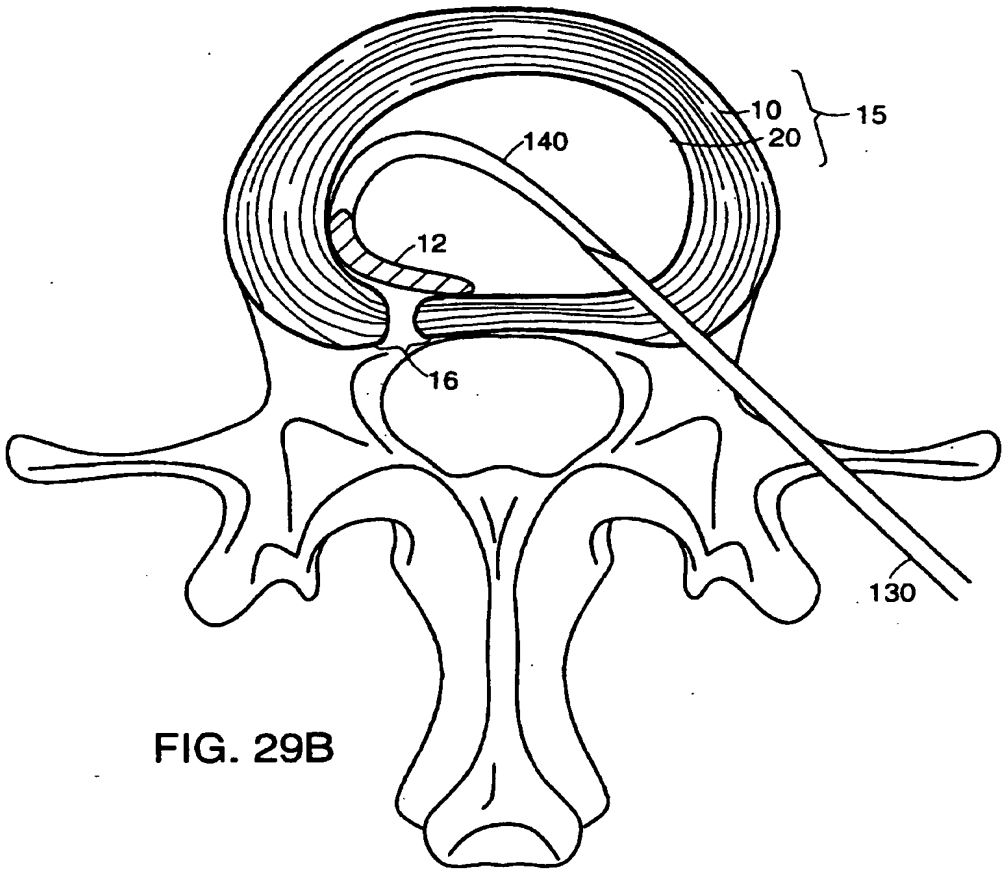

FIG. 29B

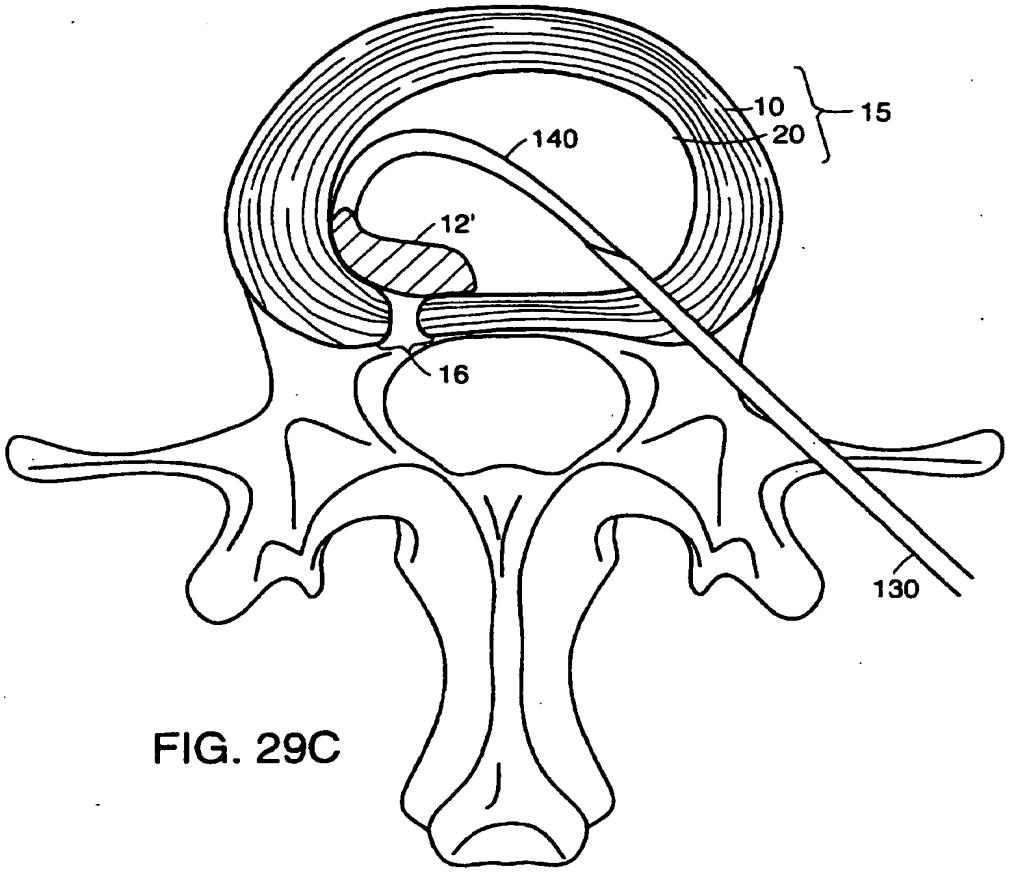

FIG. 29C

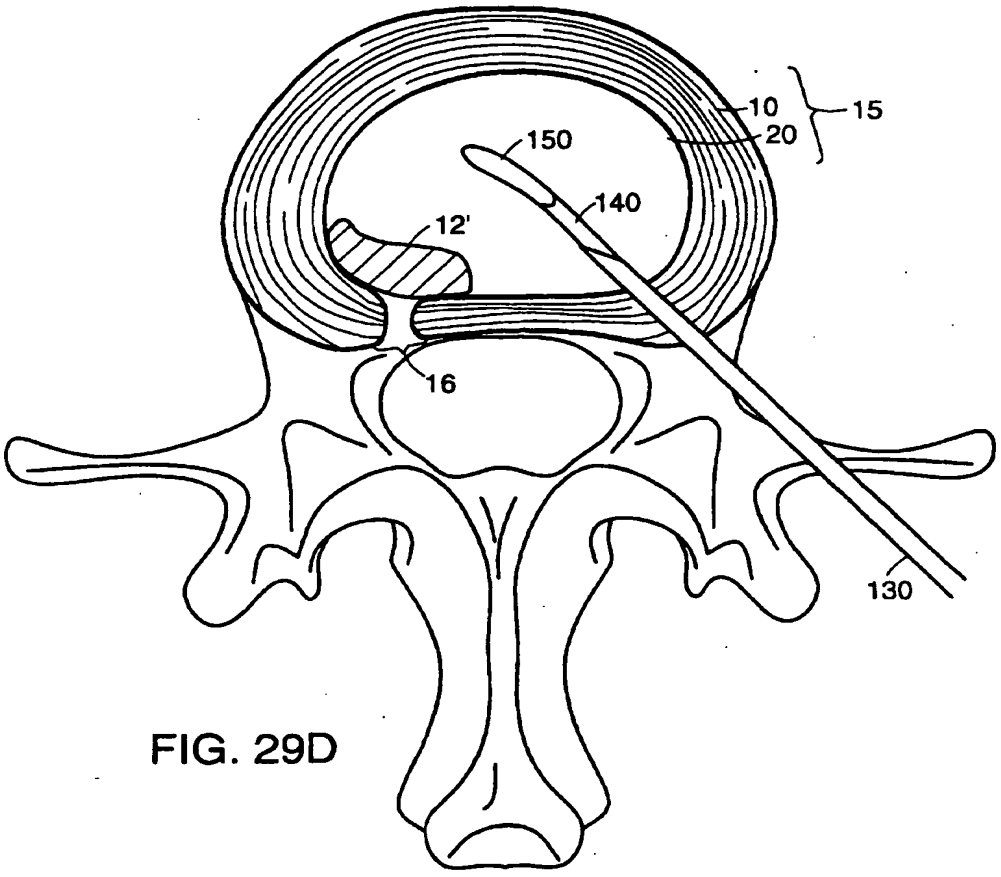

FIG. 29D

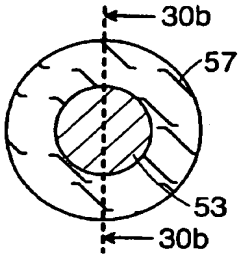

FIG. 30A

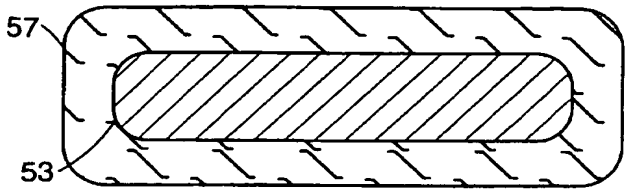

FIG. 30B

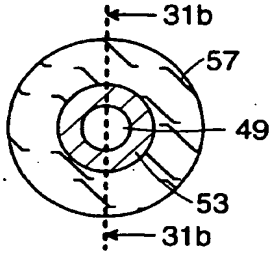

FIG. 31A

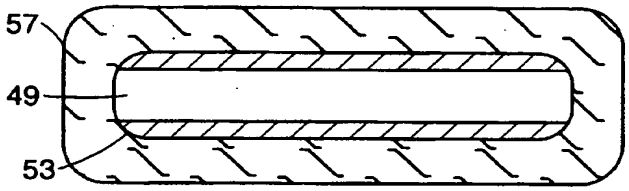

FIG. 31B

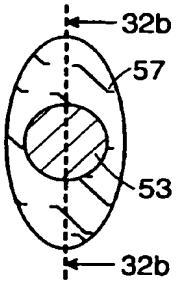

FIG. 32A

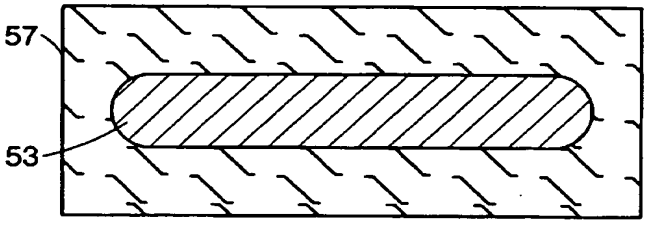

FIG. 32B

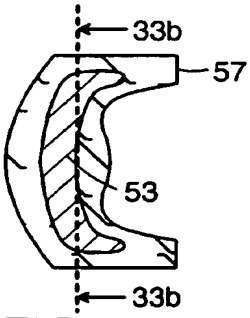

FIG. 33A

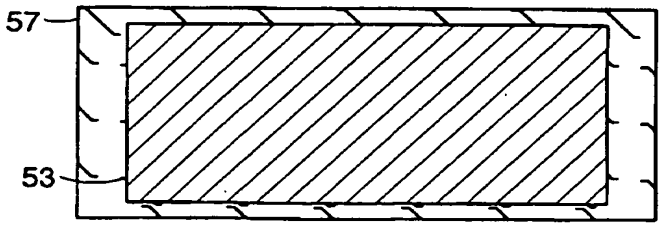

FIG. 33B

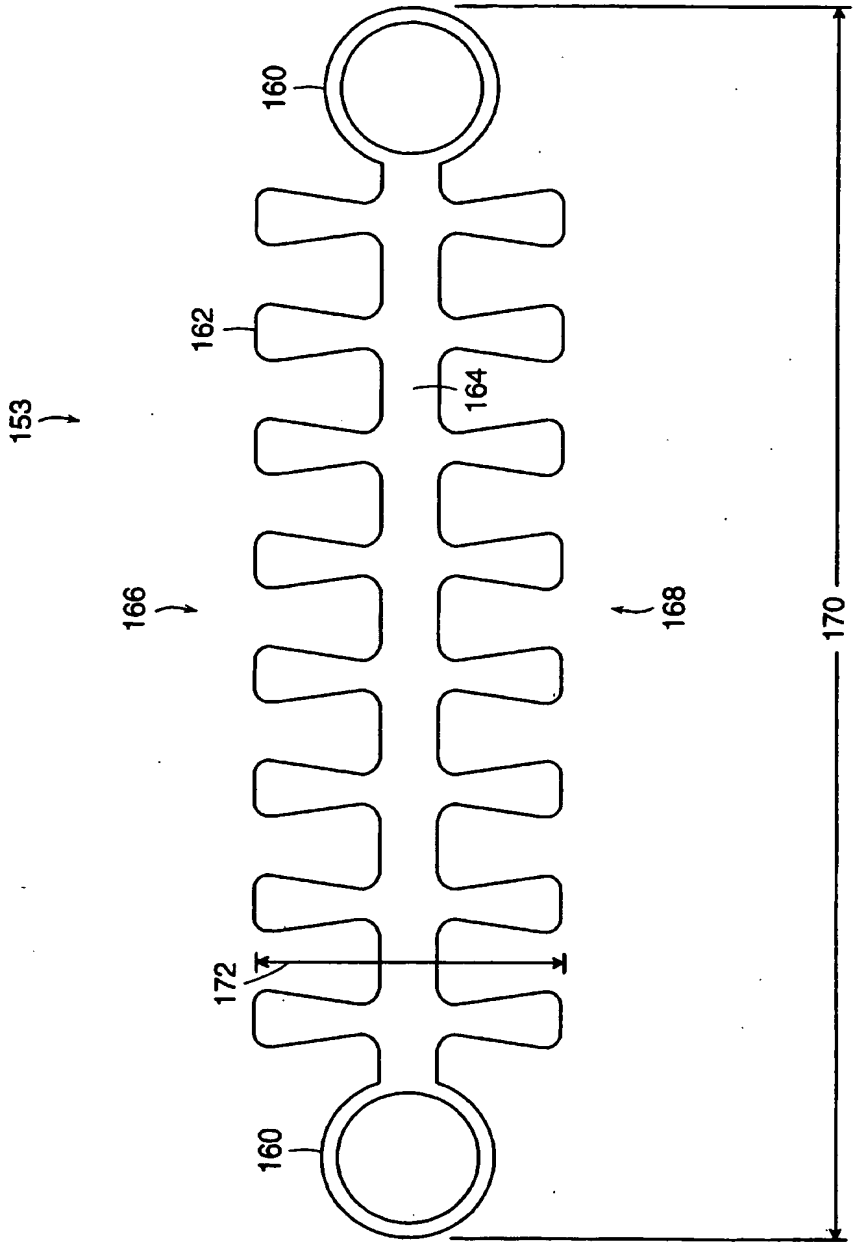

FIG. 34A

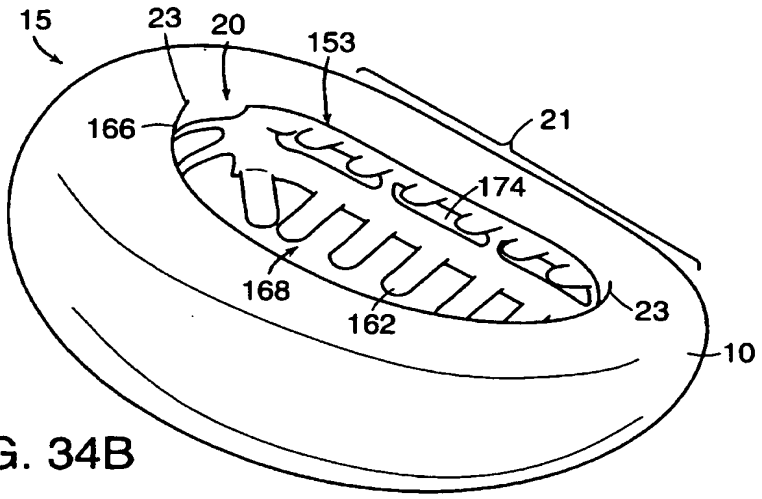

FIG. 34B

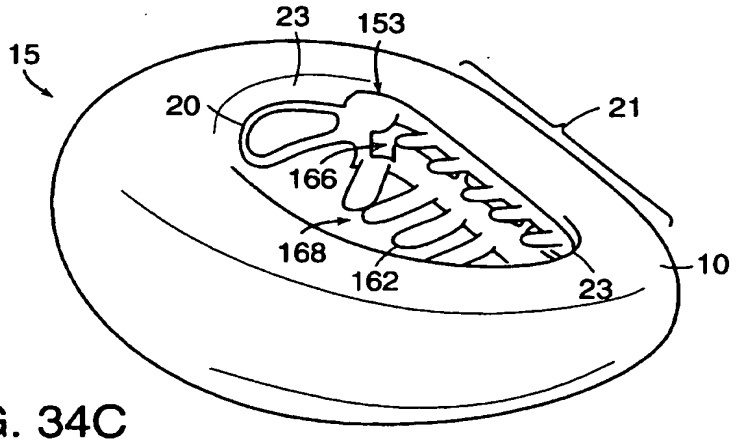

FIG. 34C

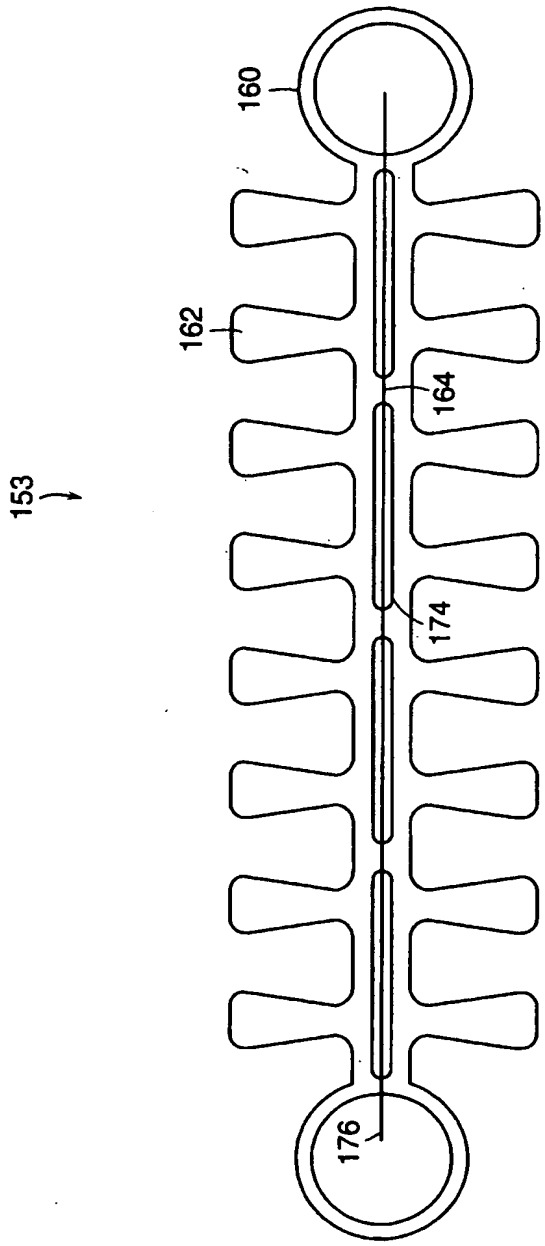

FIG. 35

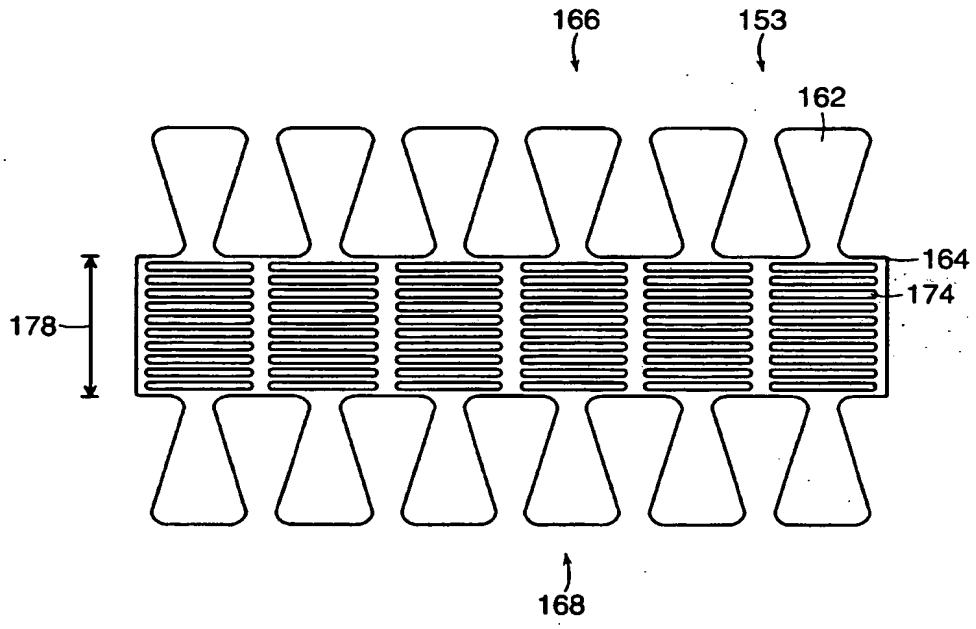

FIG. 36

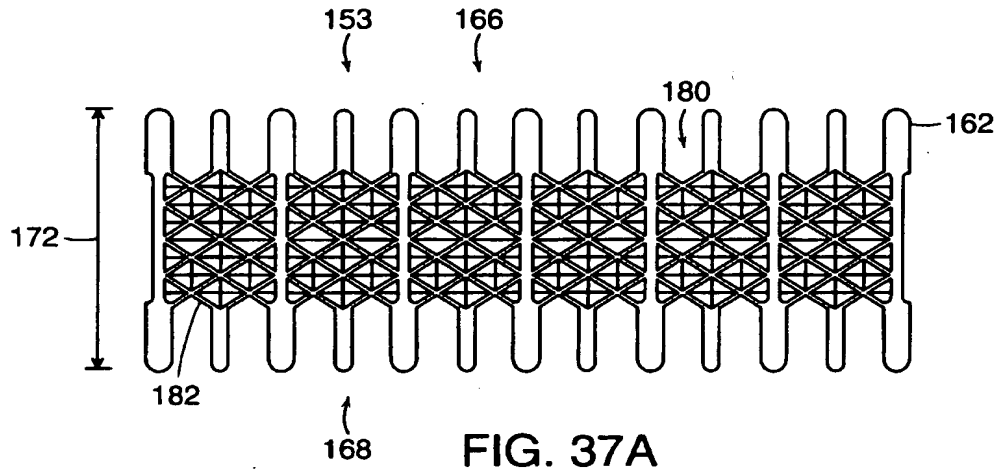

FIG. 37A

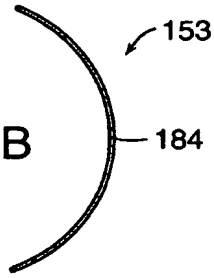

FIG. 37B

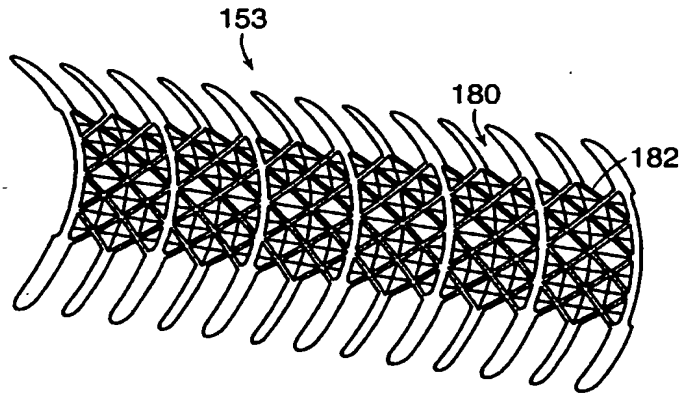

FIG. 37C

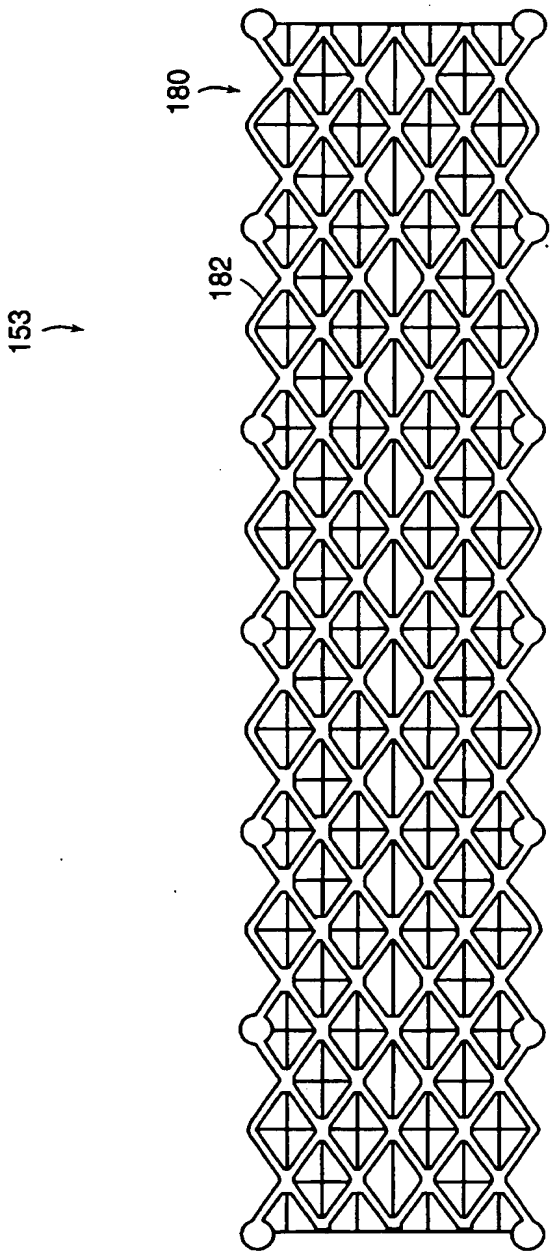

FIG. 38

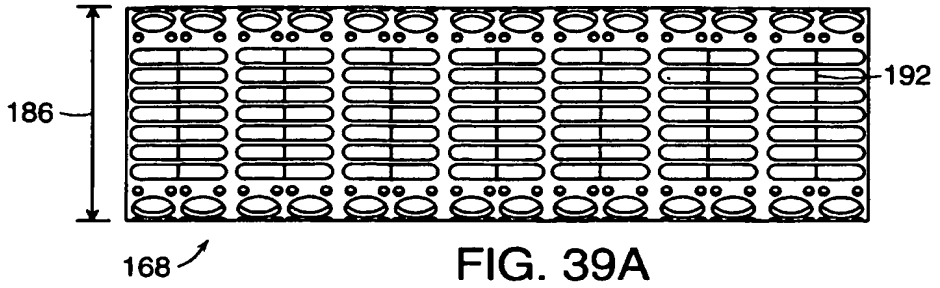

FIG. 39A

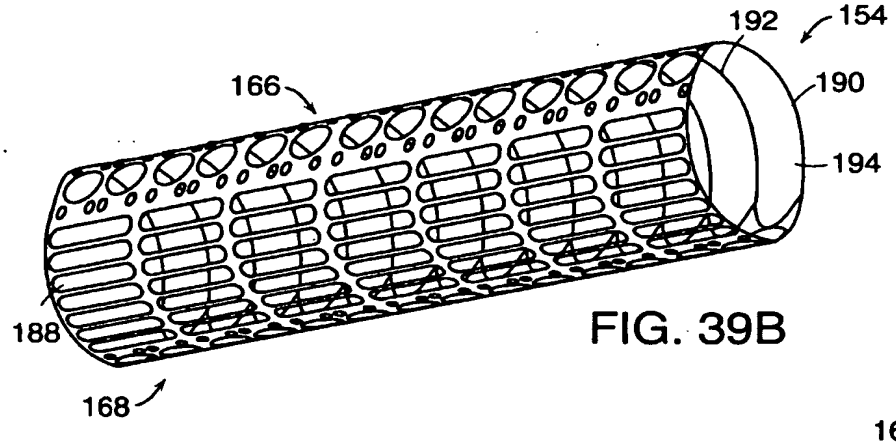

FIG. 39B

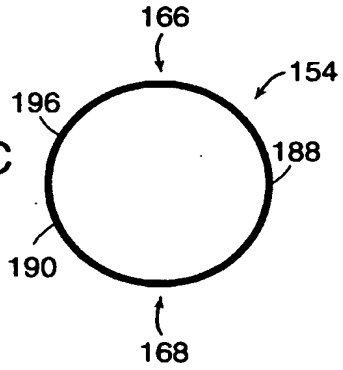

FIG. 39C

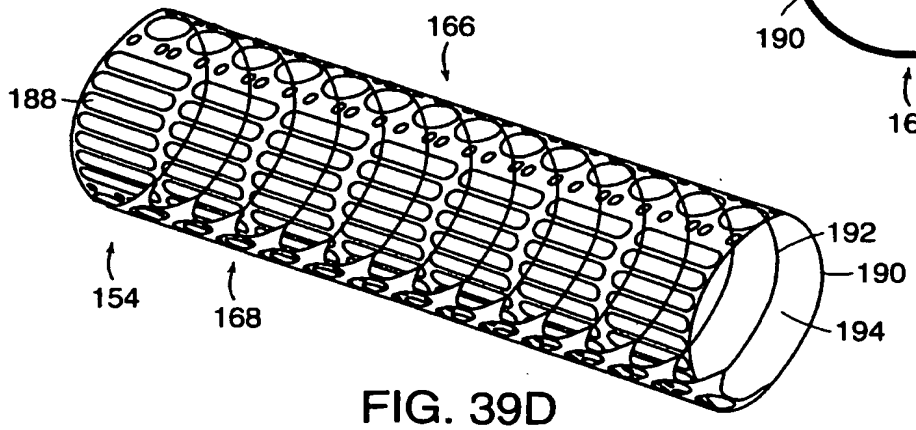

FIG. 39D

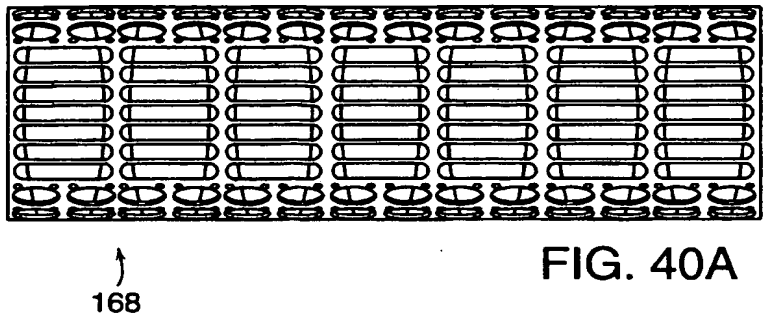

FIG. 40A

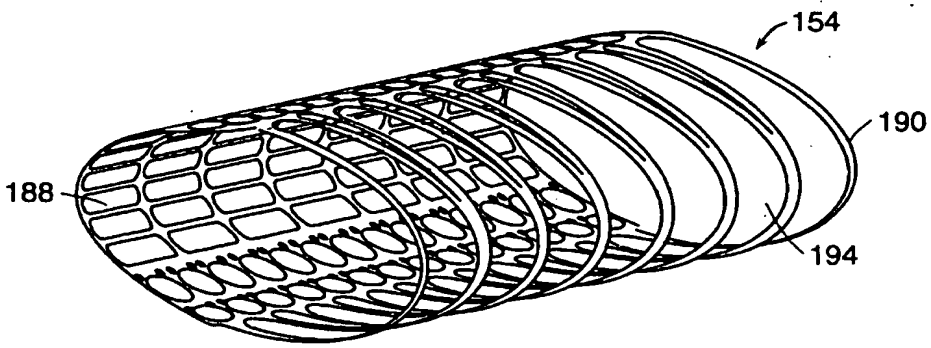

FIG. 40B

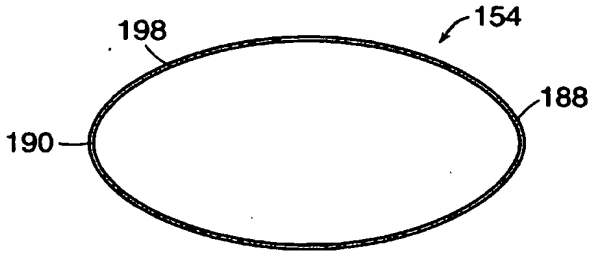

FIG. 40C

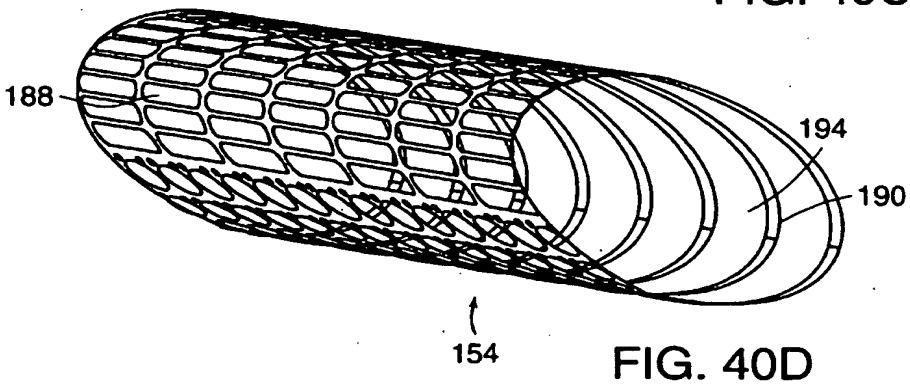

FIG. 40D

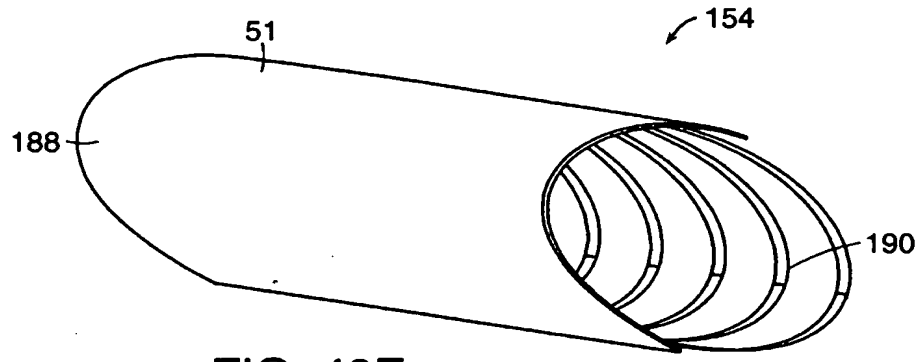

FIG. 40E

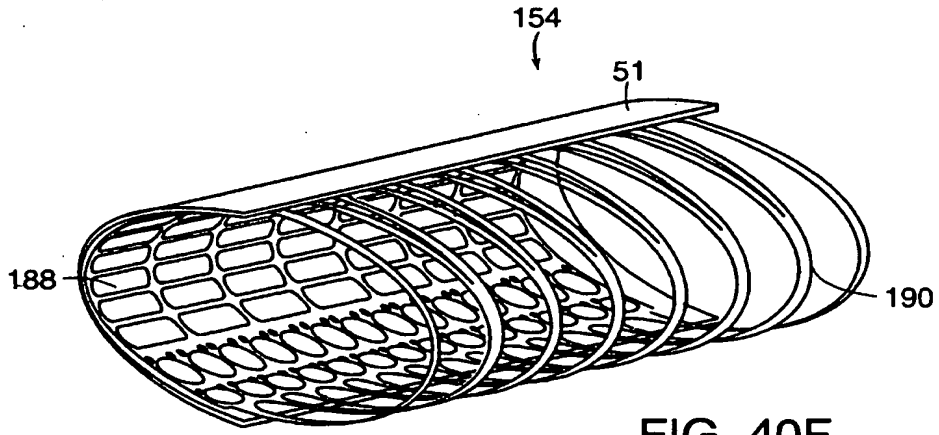

FIG. 40F

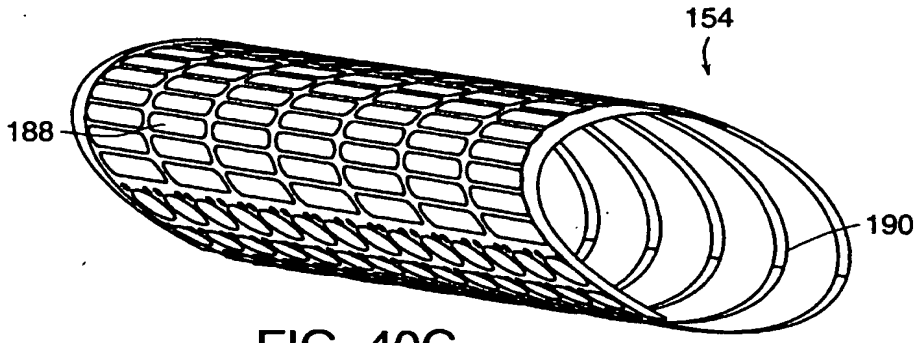

FIG. 40G

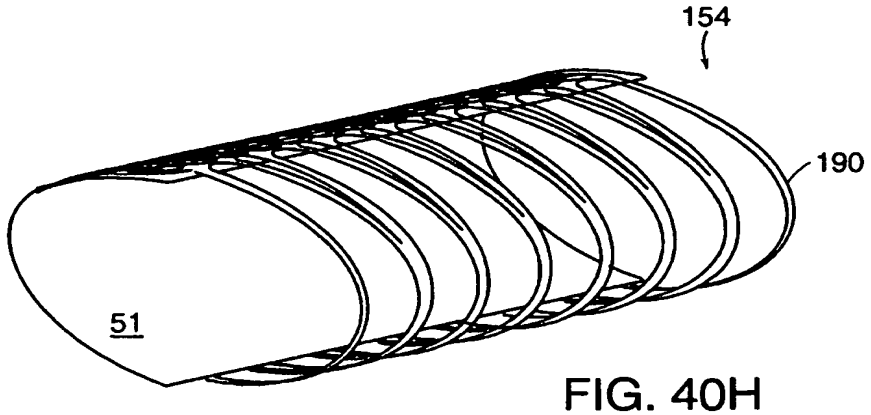

FIG. 40H

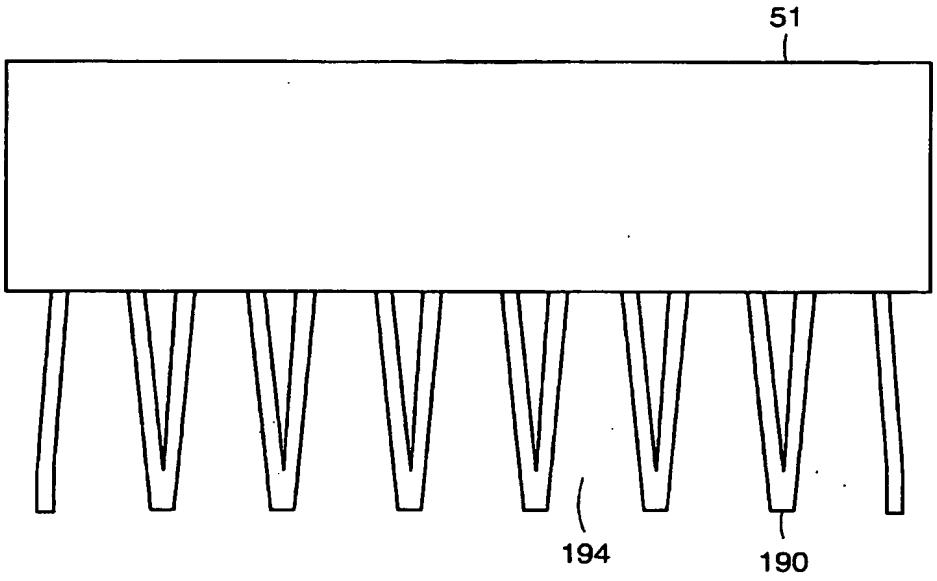

FIG. 40I

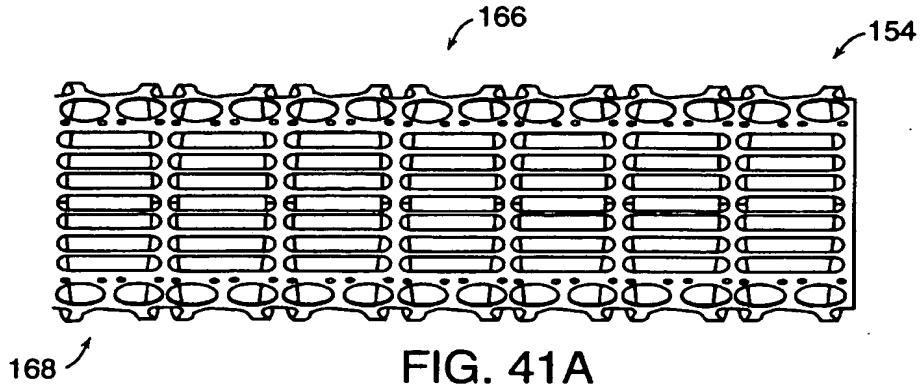

FIG. 41A

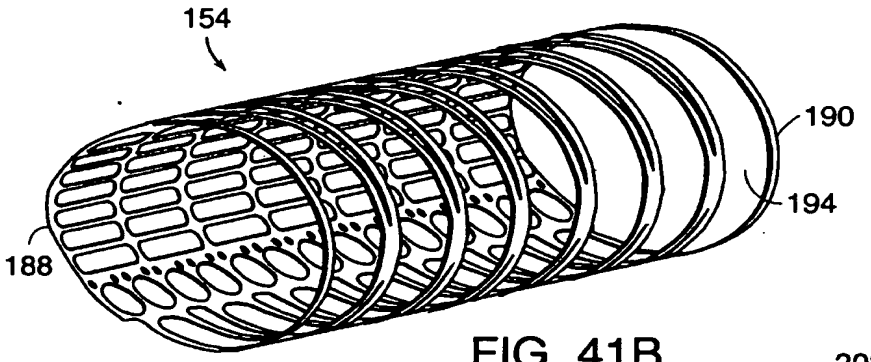

FIG. 41B

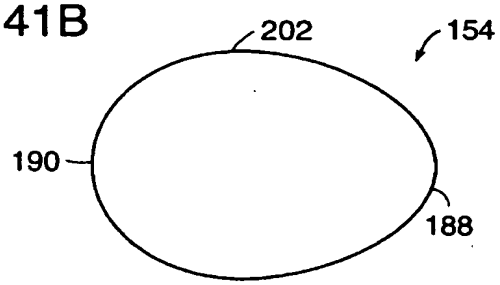

FIG. 41C

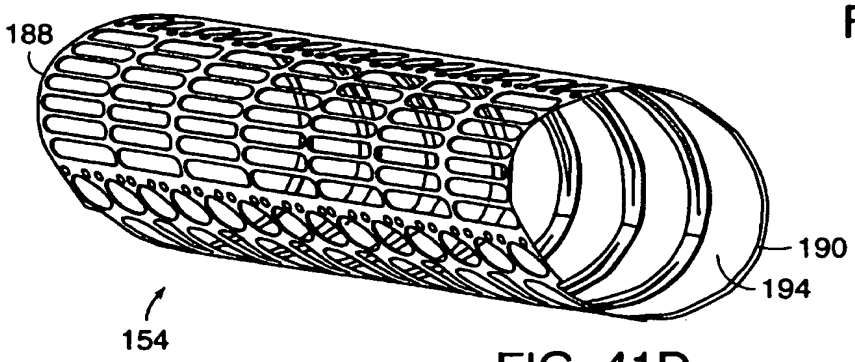

FIG. 41D

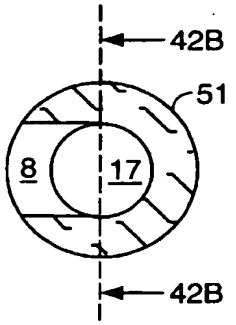

FIG. 42A

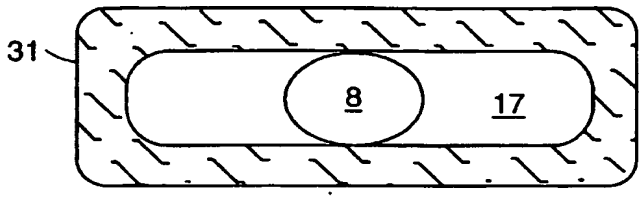

FIG. 42B

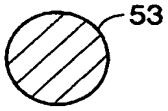

FIG. 42C

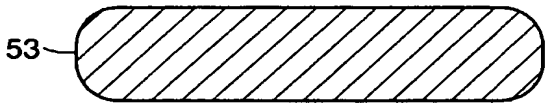

FIG. 42D

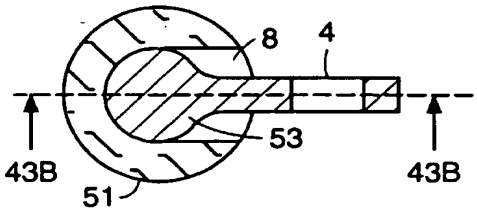

FIG. 43A

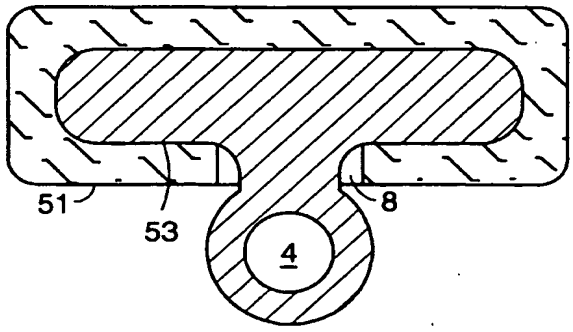

FIG. 43B

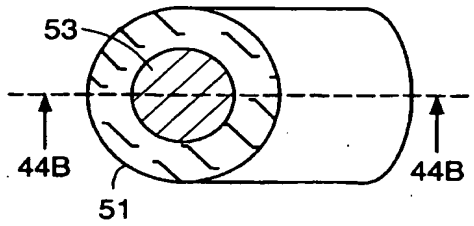

FIG. 44A

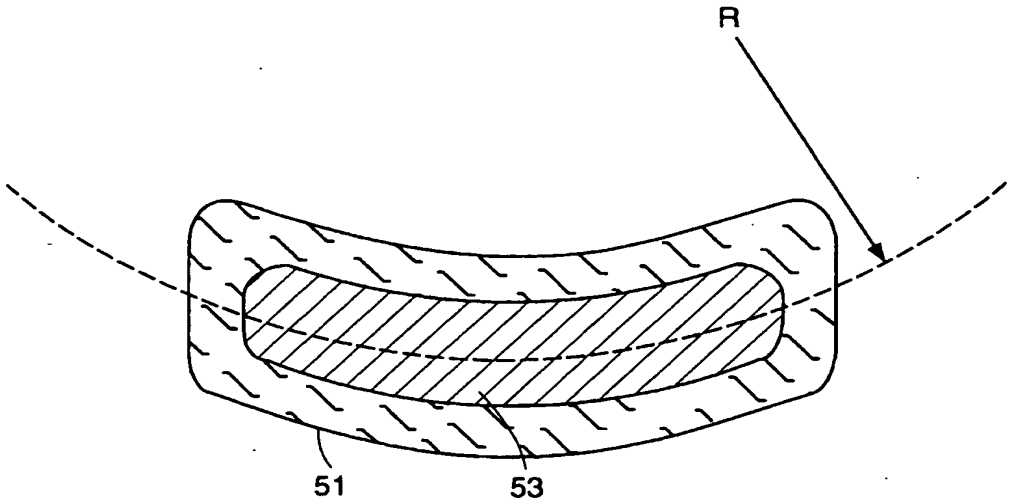

FIG. 44B

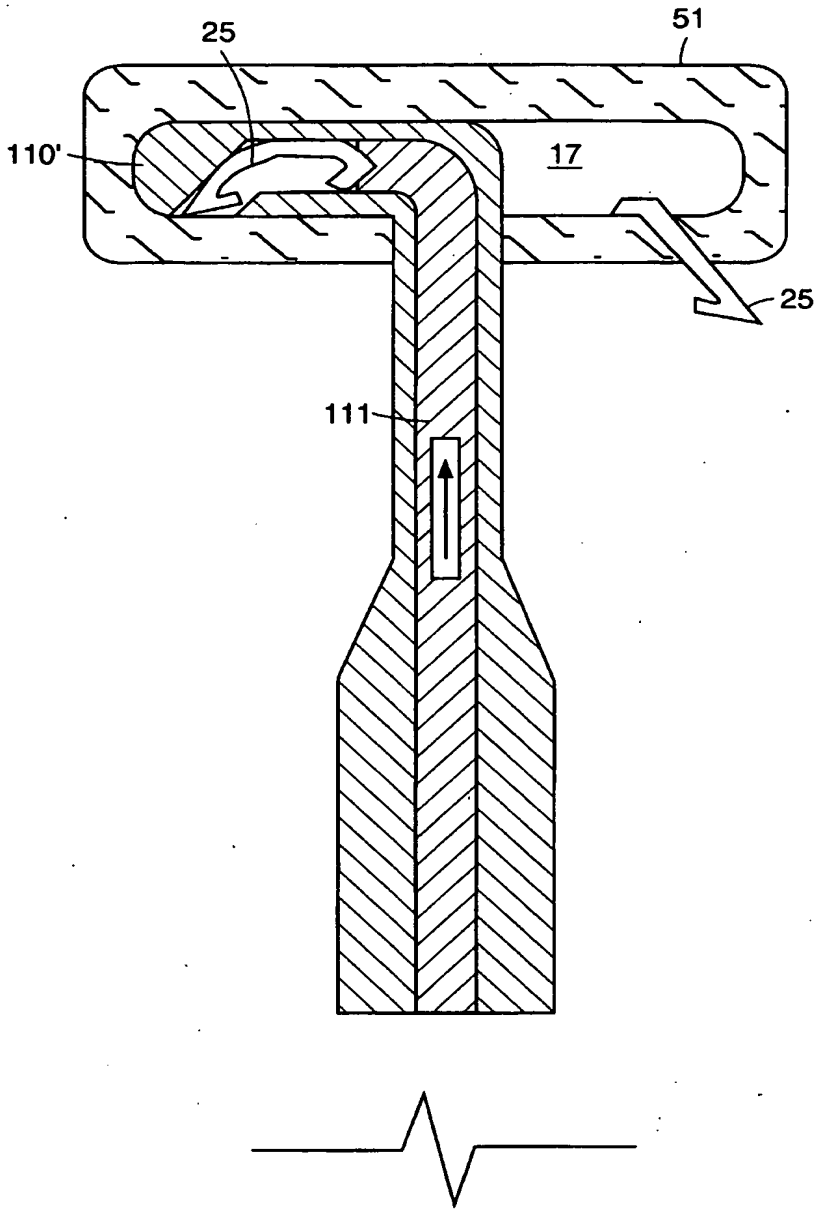

FIG. 45

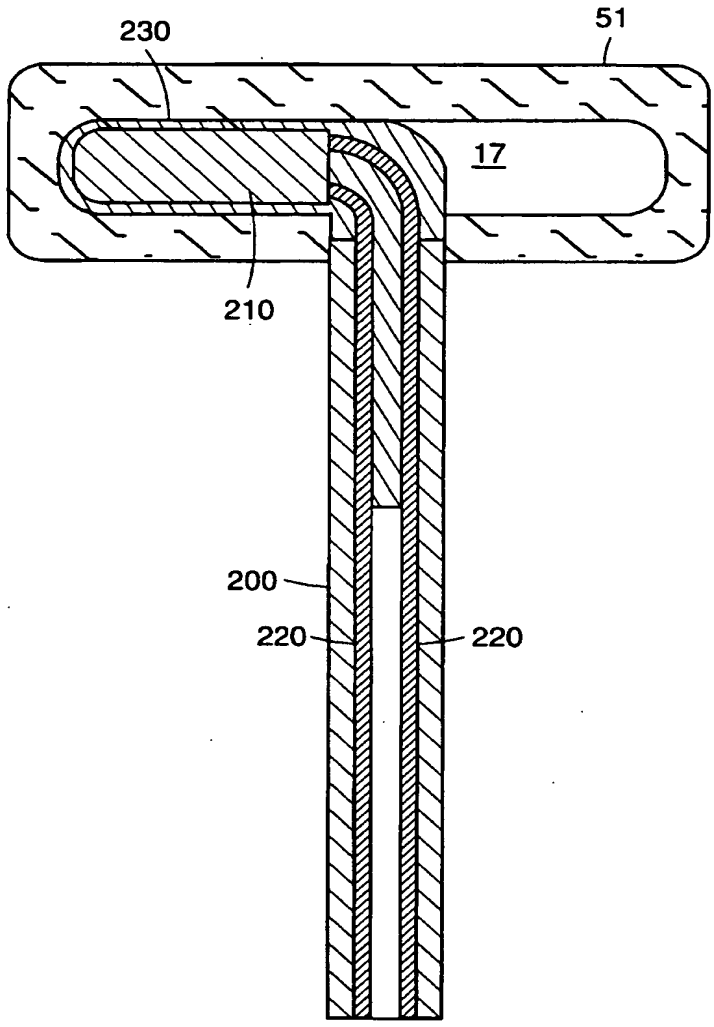

FIG. 46

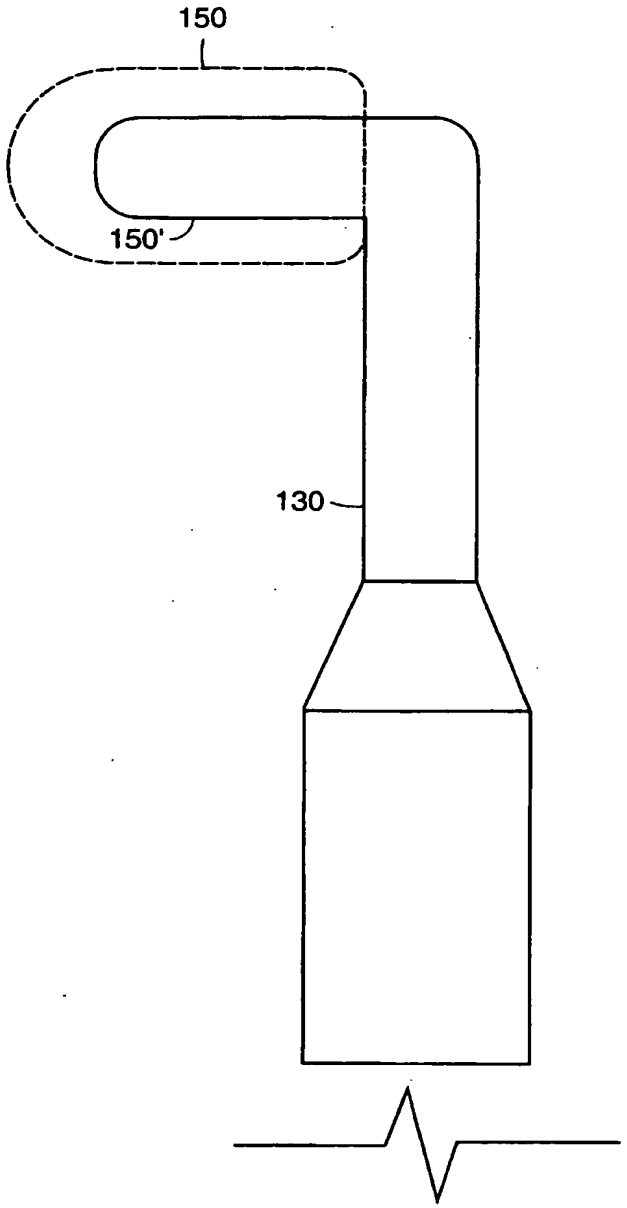

FIG. 47

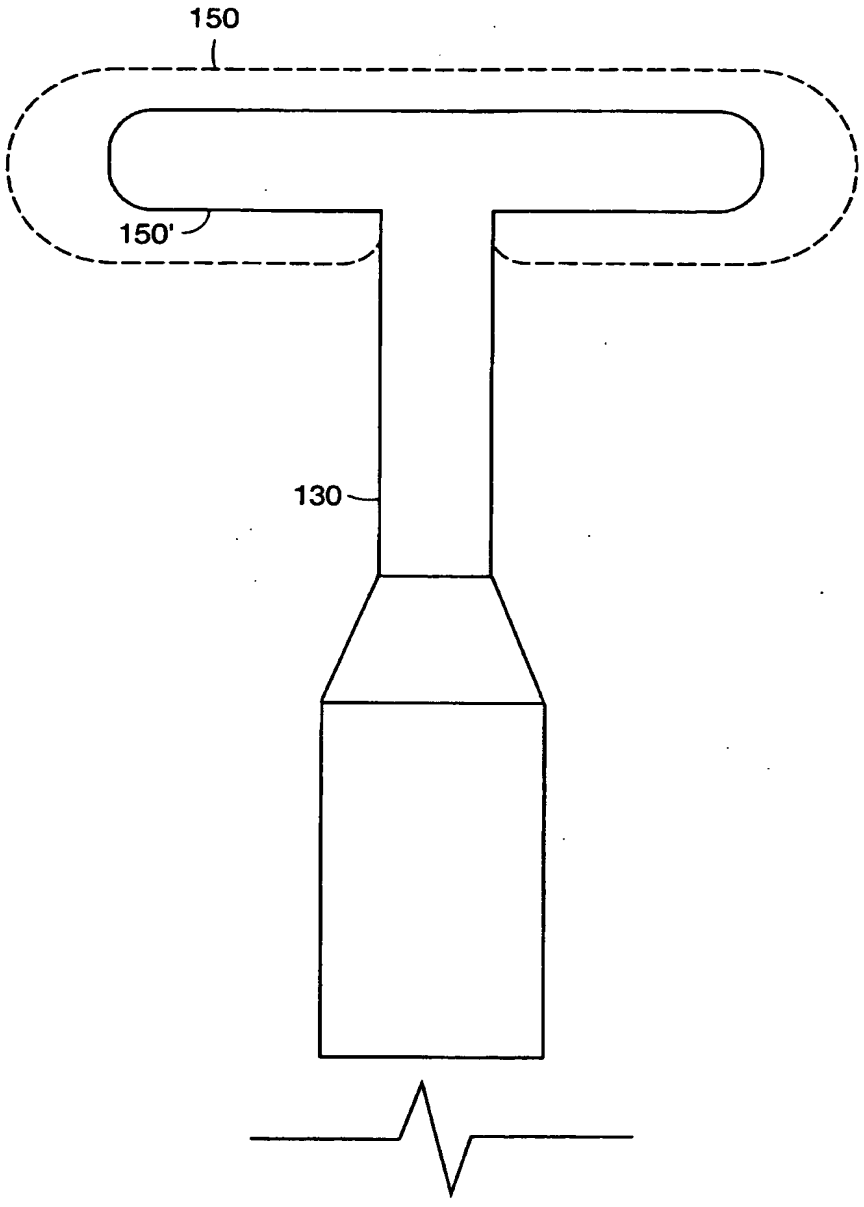

FIG. 48

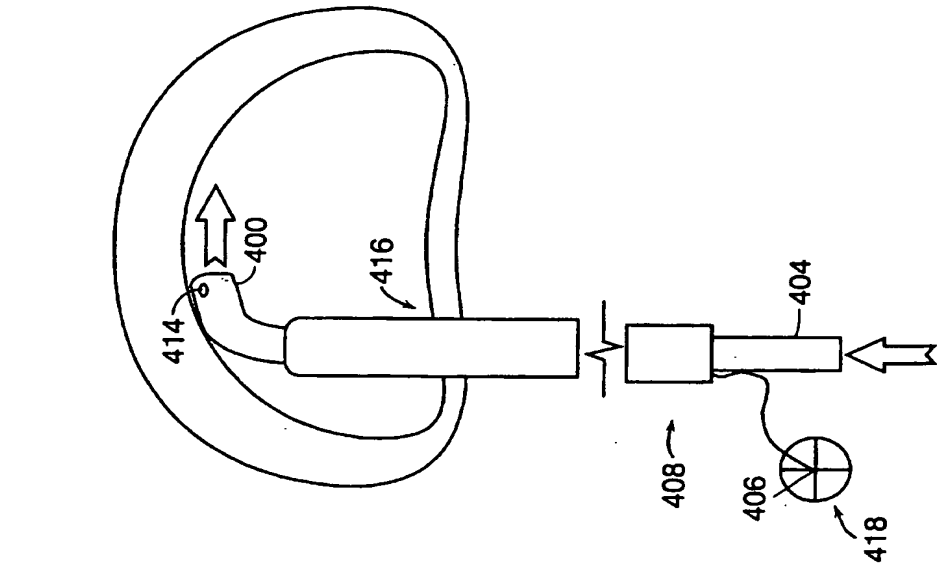

FIG. 49B

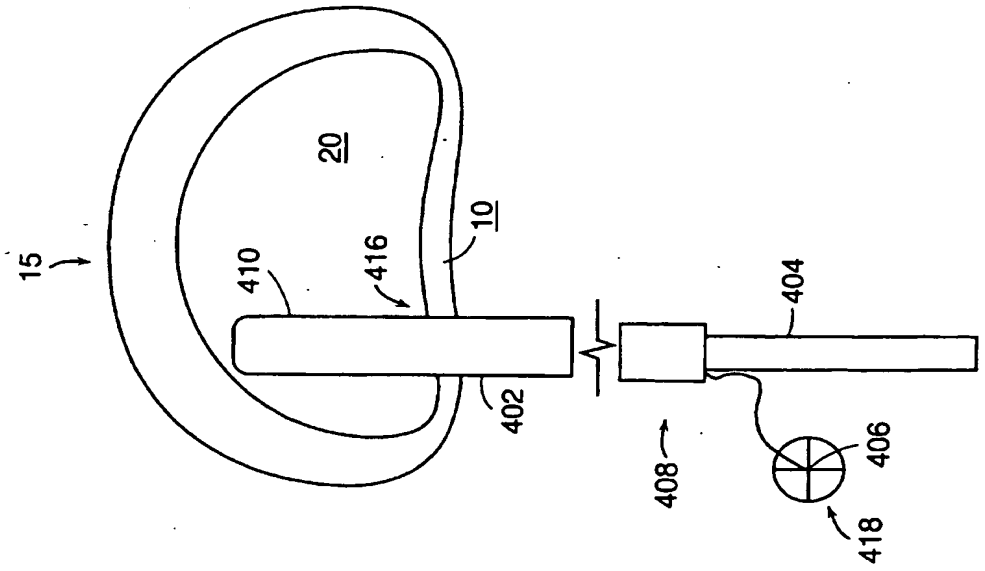

FIG. 49A

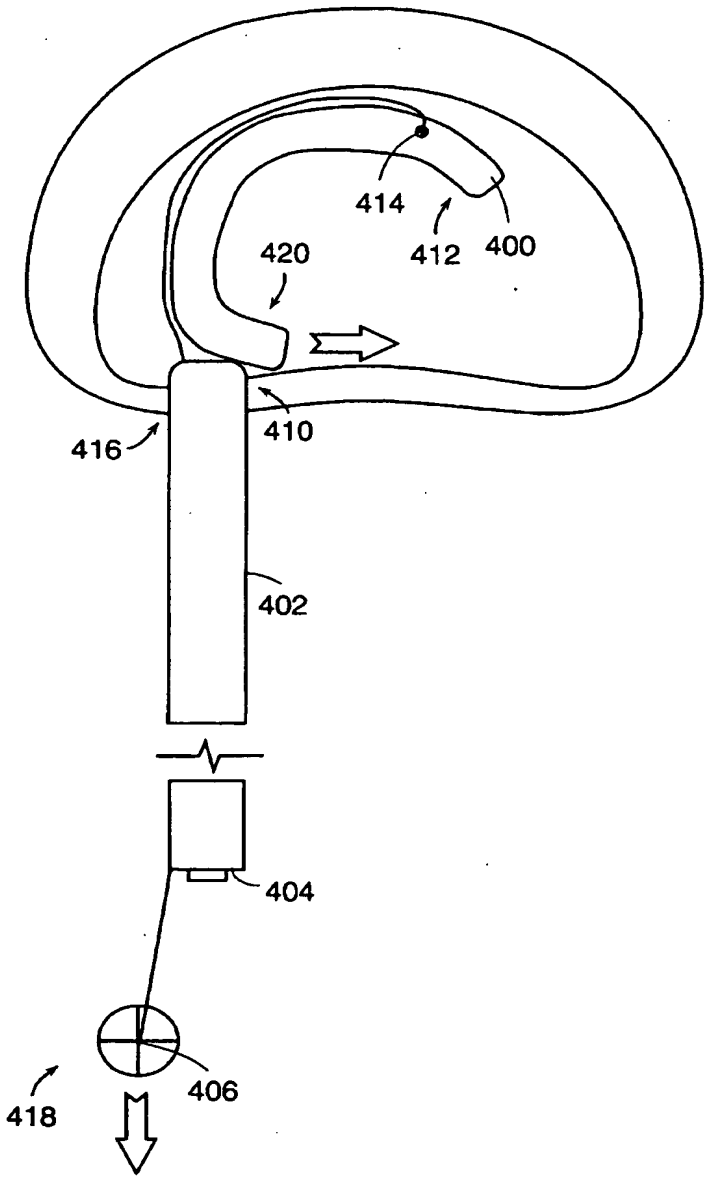

FIG. 49C

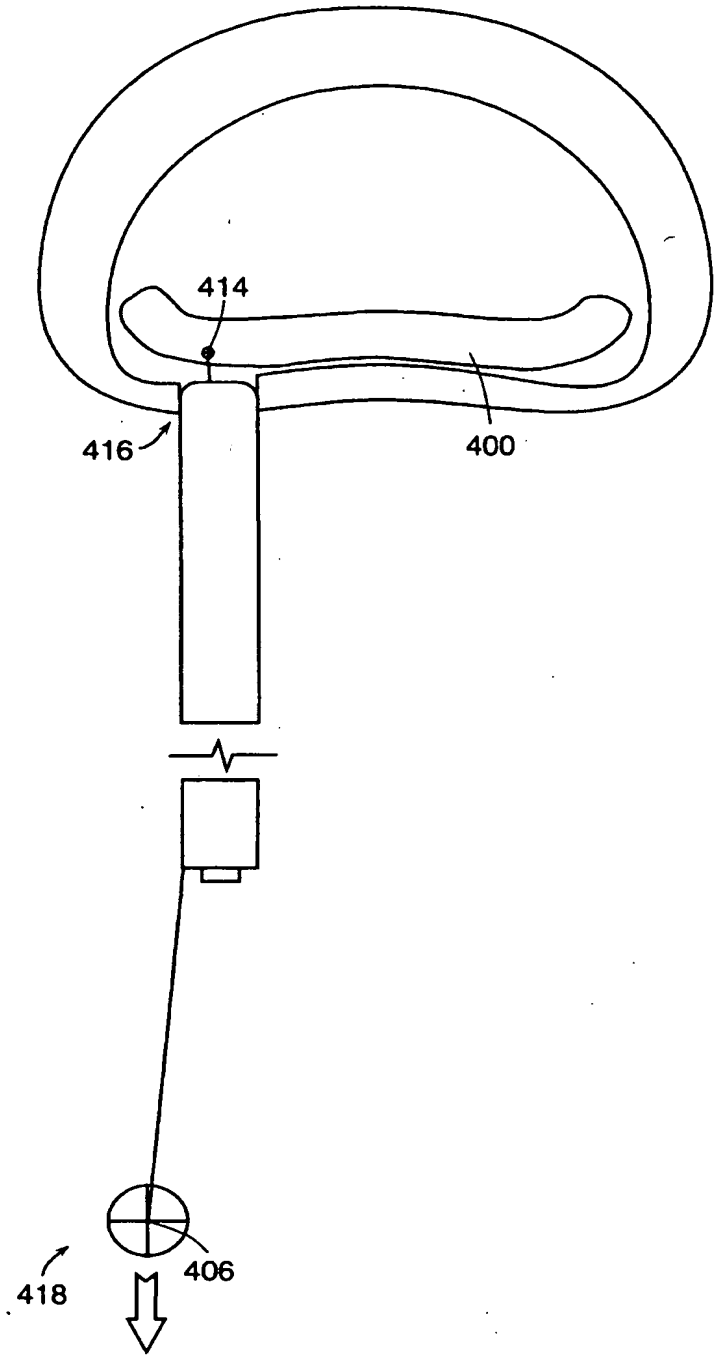

FIG. 49D

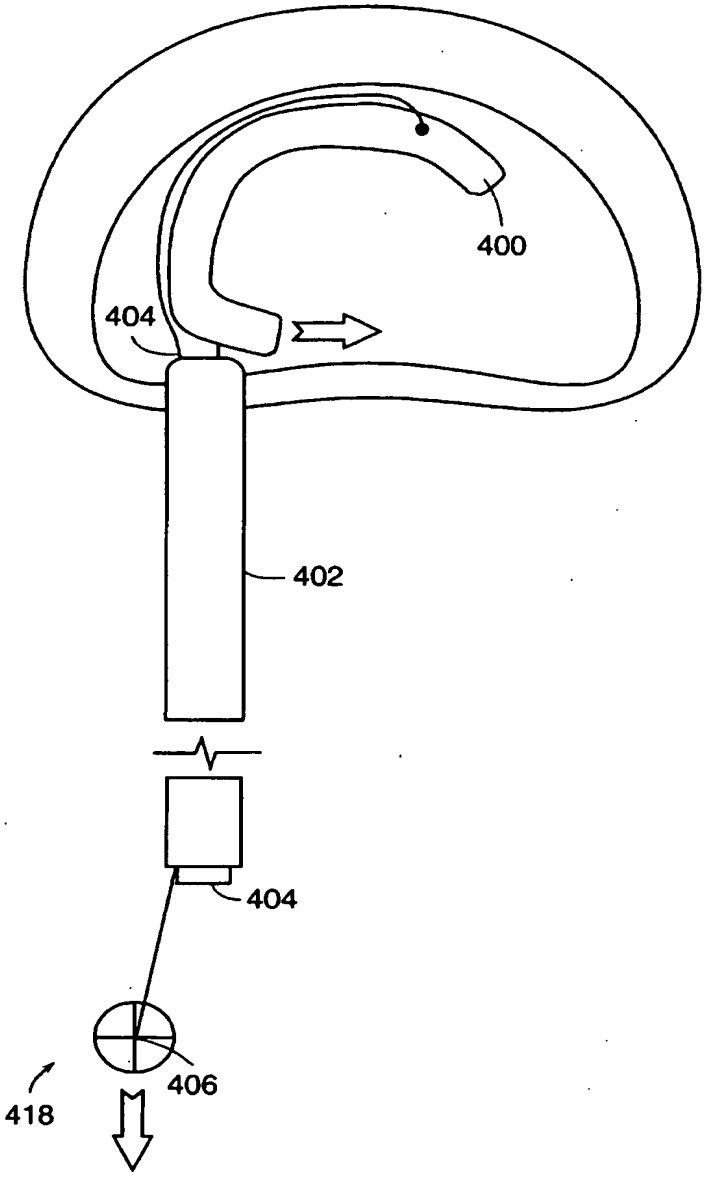

FIG. 49E

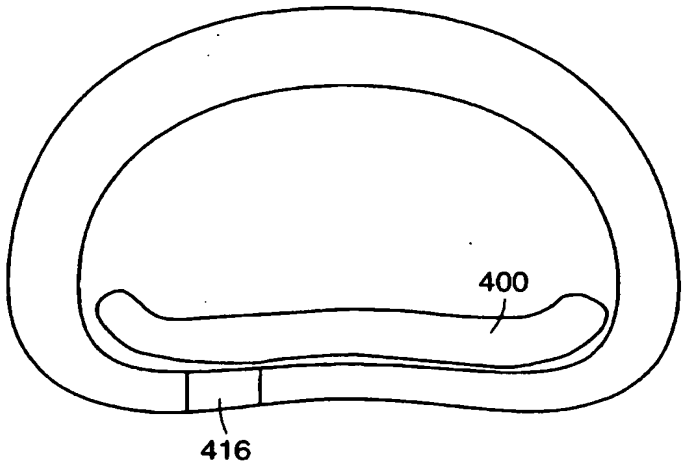

FIG. 49F

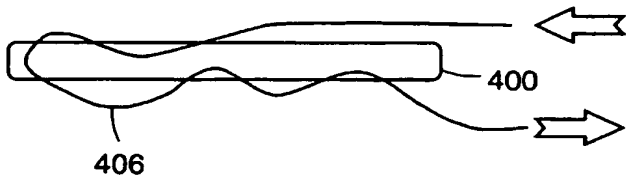

FIG. 49G

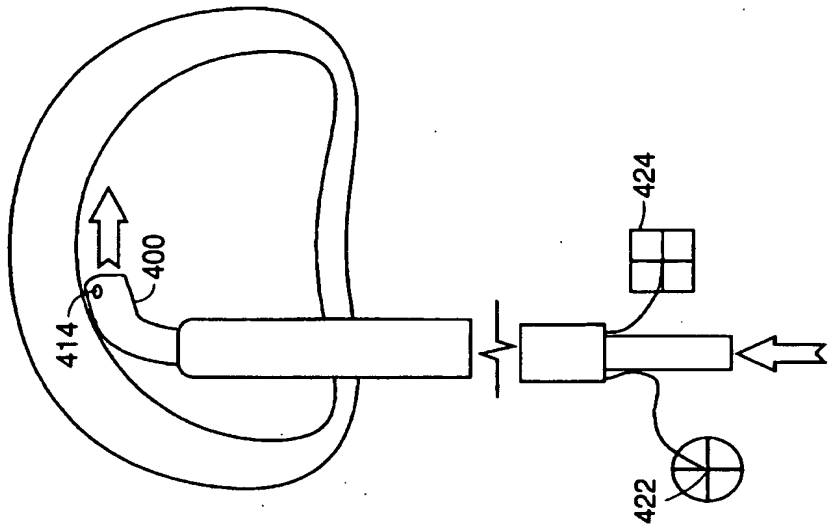

FIG. 50B

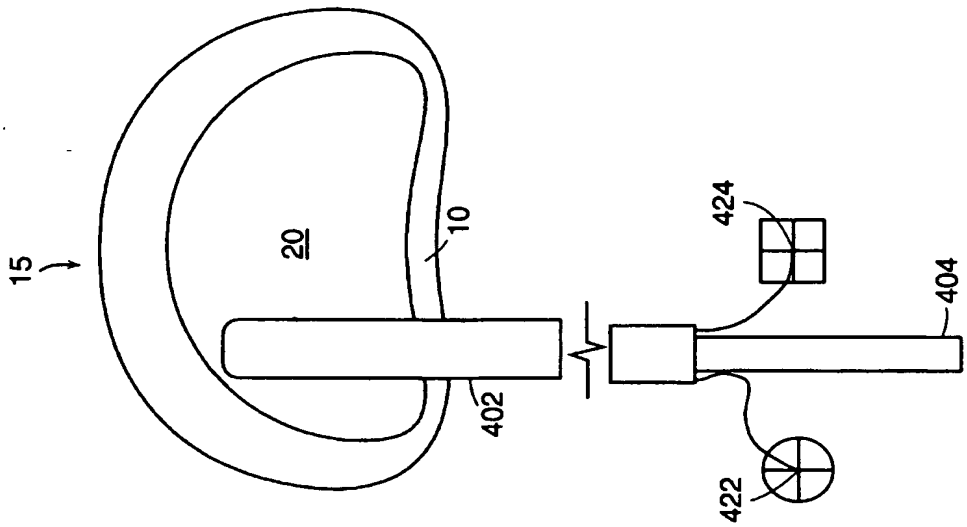

FIG. 50A

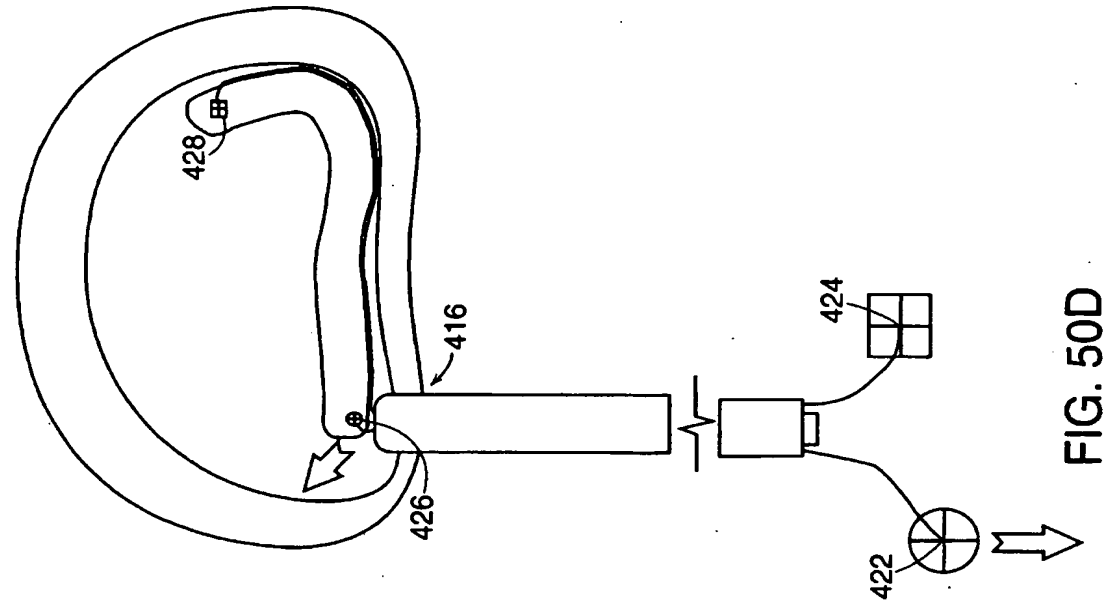

FIG. 50D

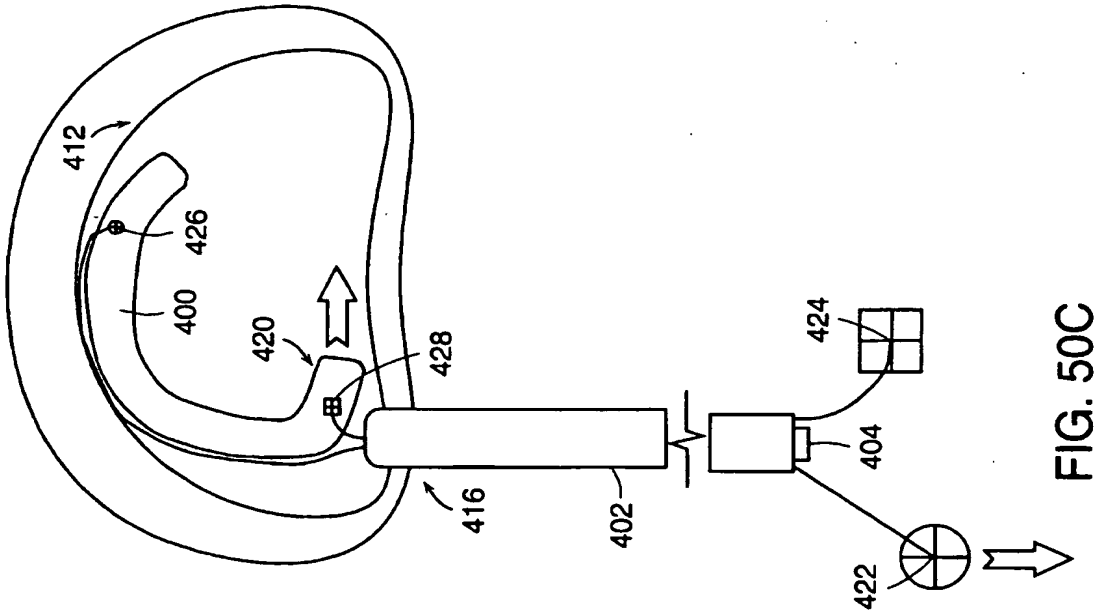

FIG. 50C

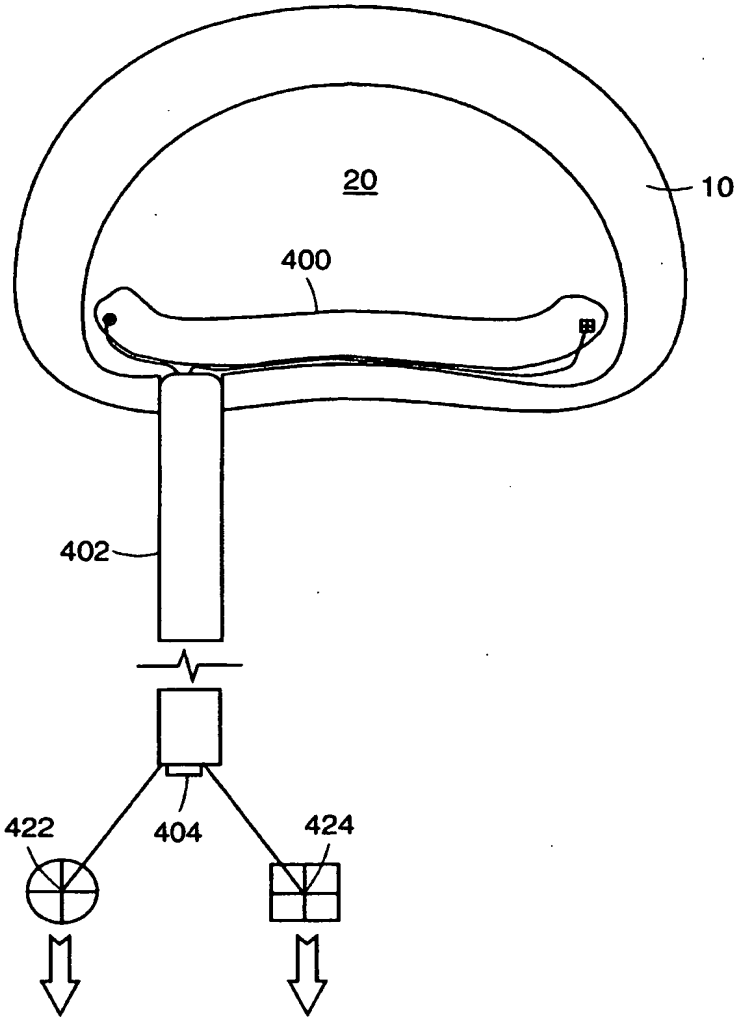

FIG. 50E

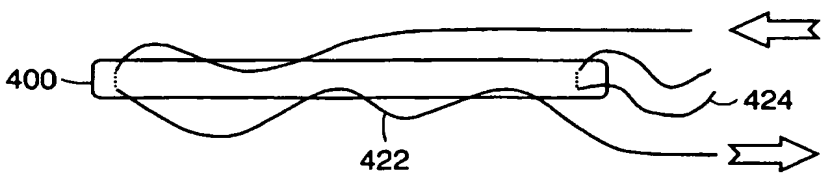

FIG. 50F

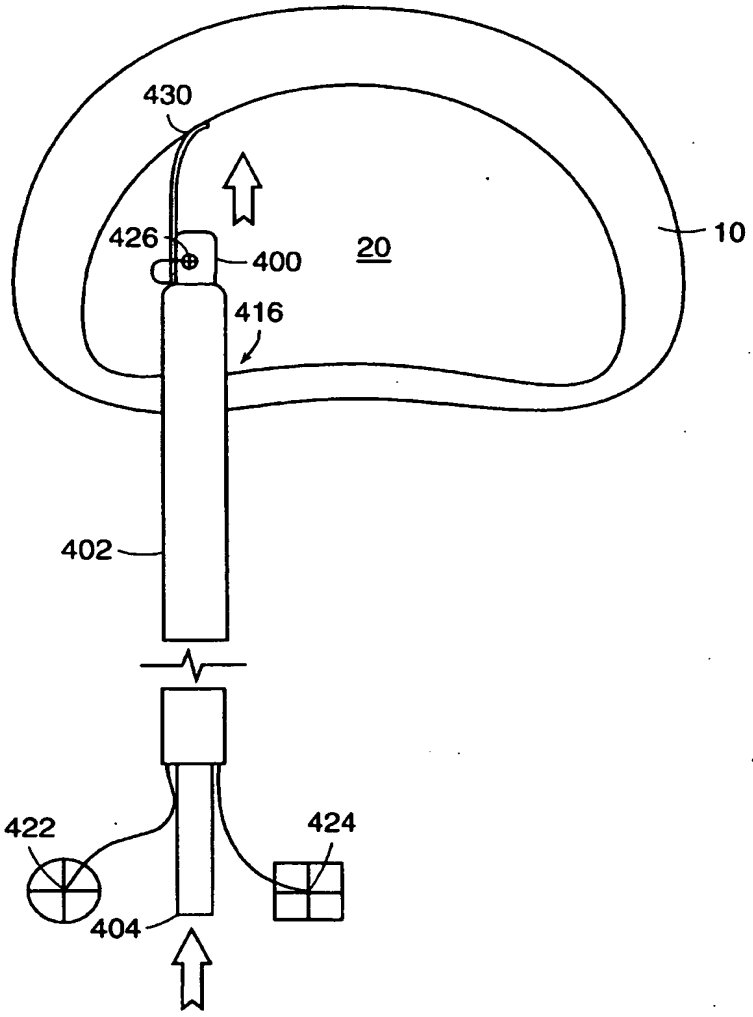

FIG. 51A

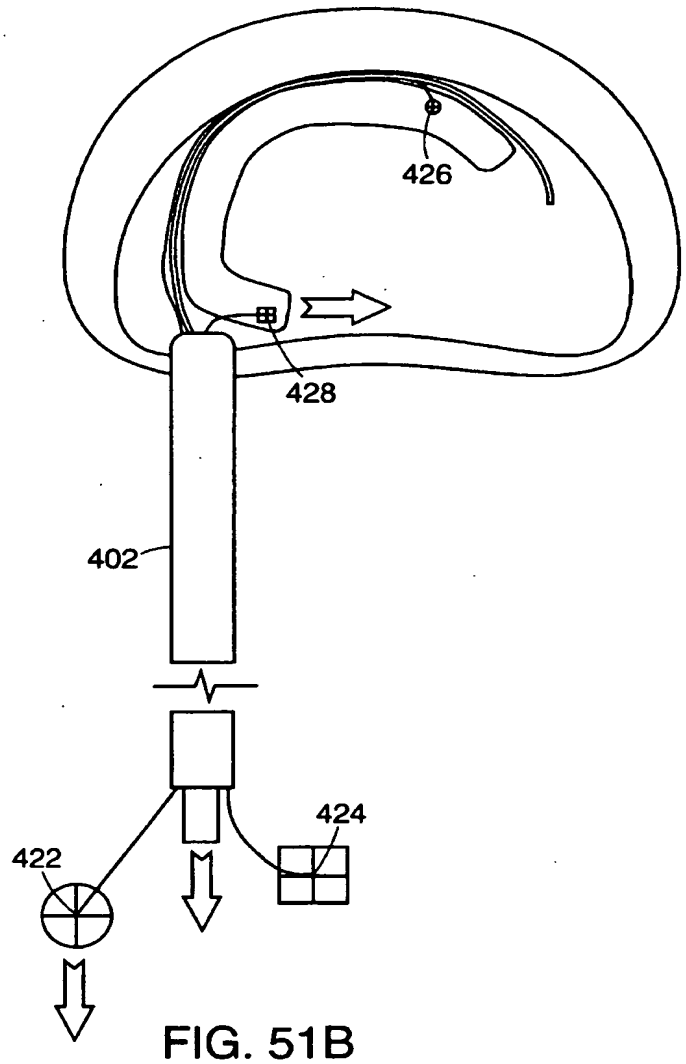

FIG. 51B

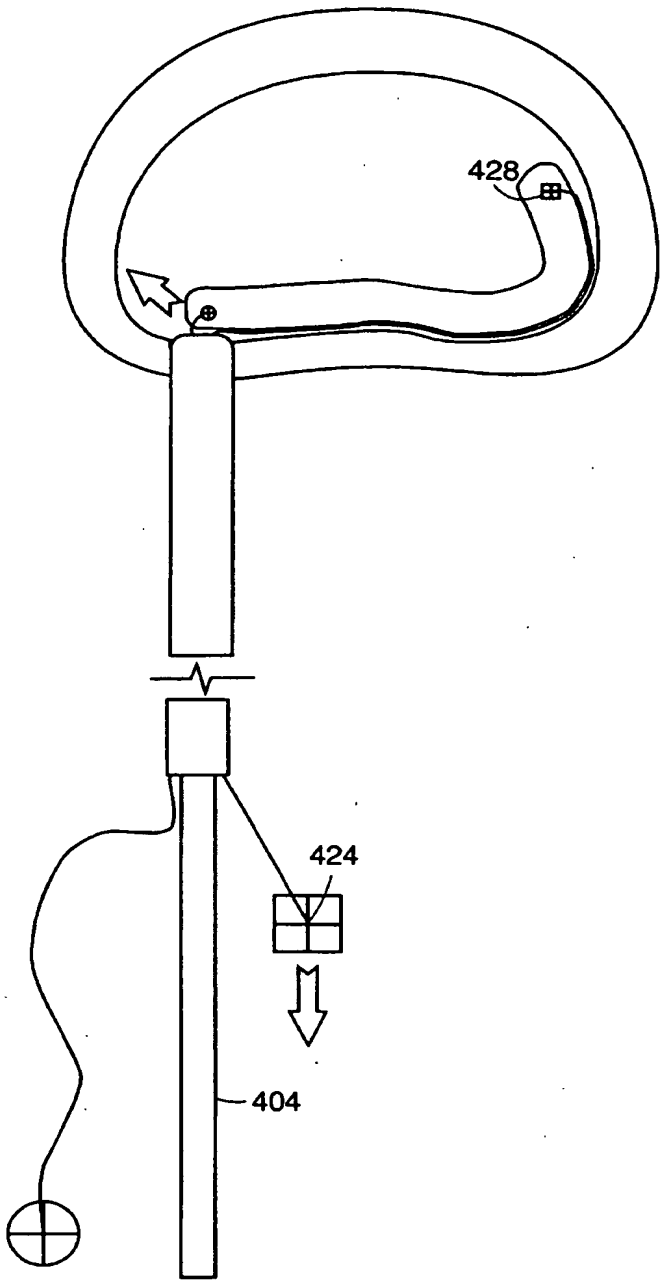

FIG. 51C

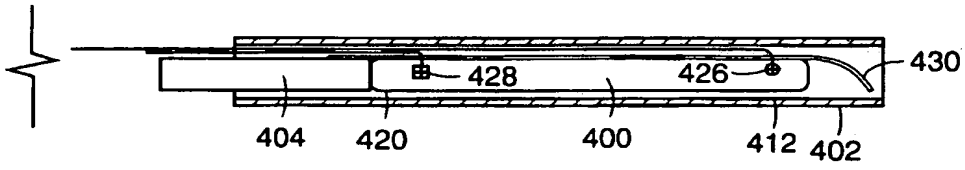

FIG. 52A

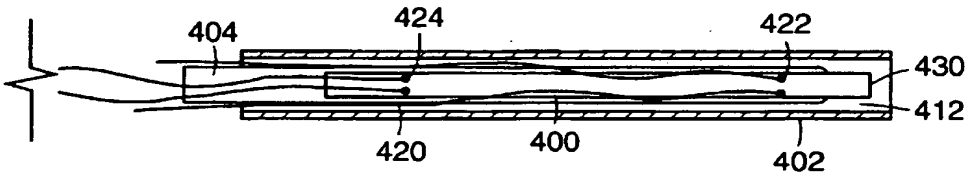

FIG. 52B

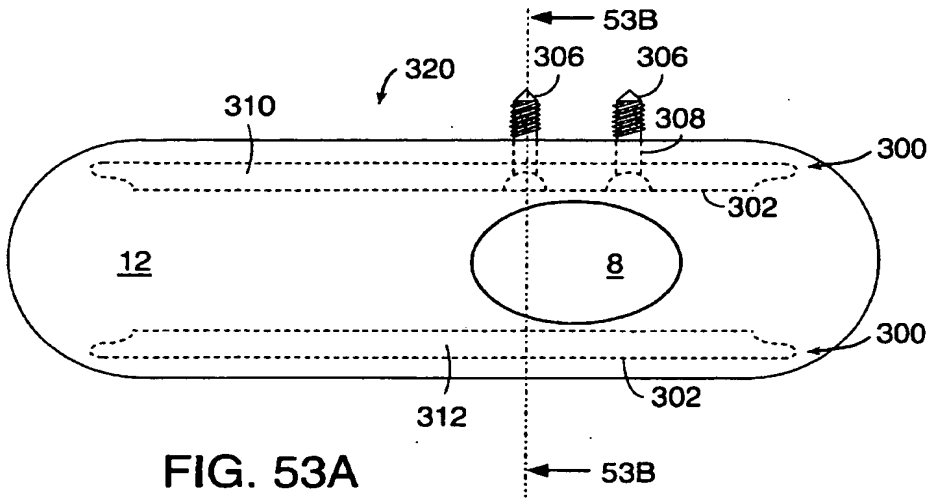

FIG. 53A

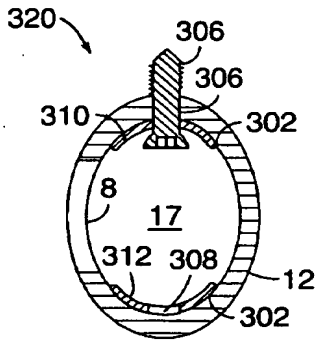

FIG. 53B

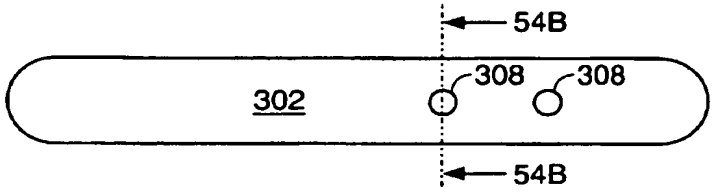

FIG. 54A

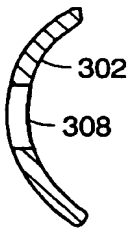

FIG. 54B

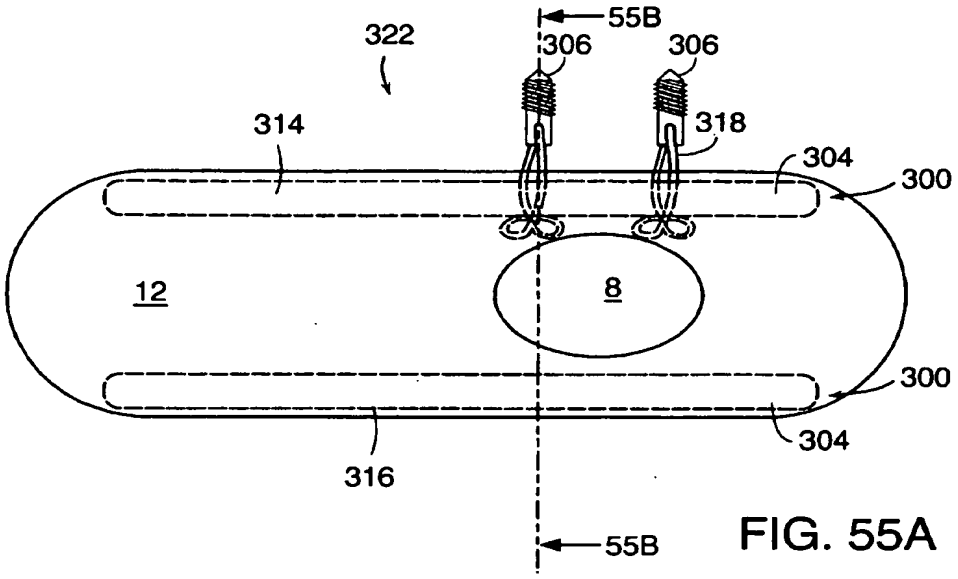

FIG. 55A

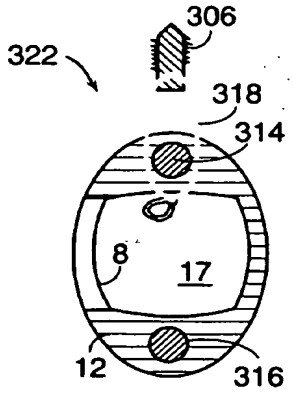

FIG. 55B

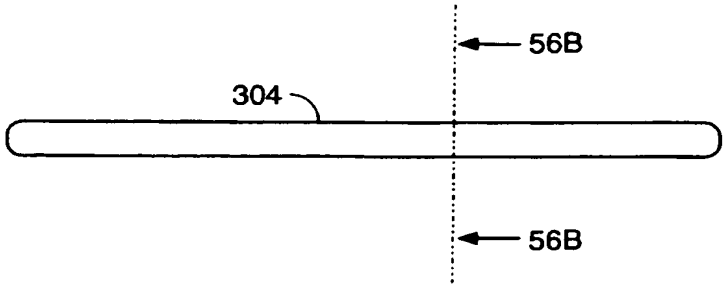

FIG. 56A

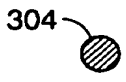

FIG. 56B

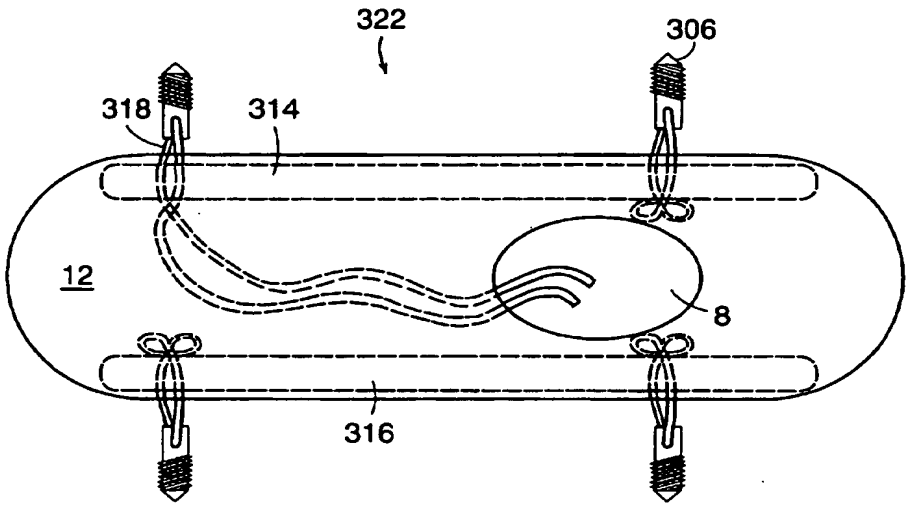

FIG. 57

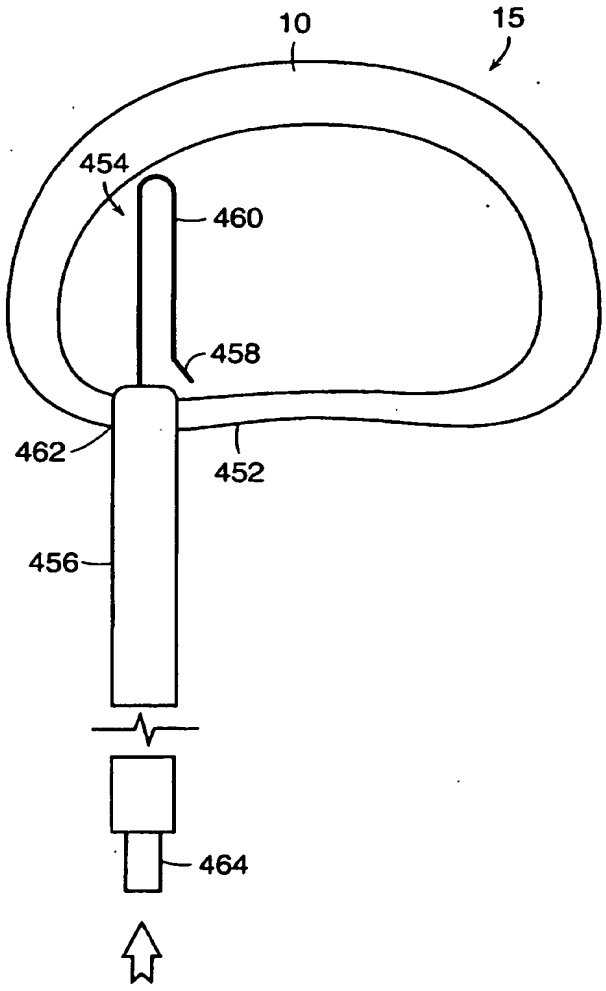

FIG. 58A

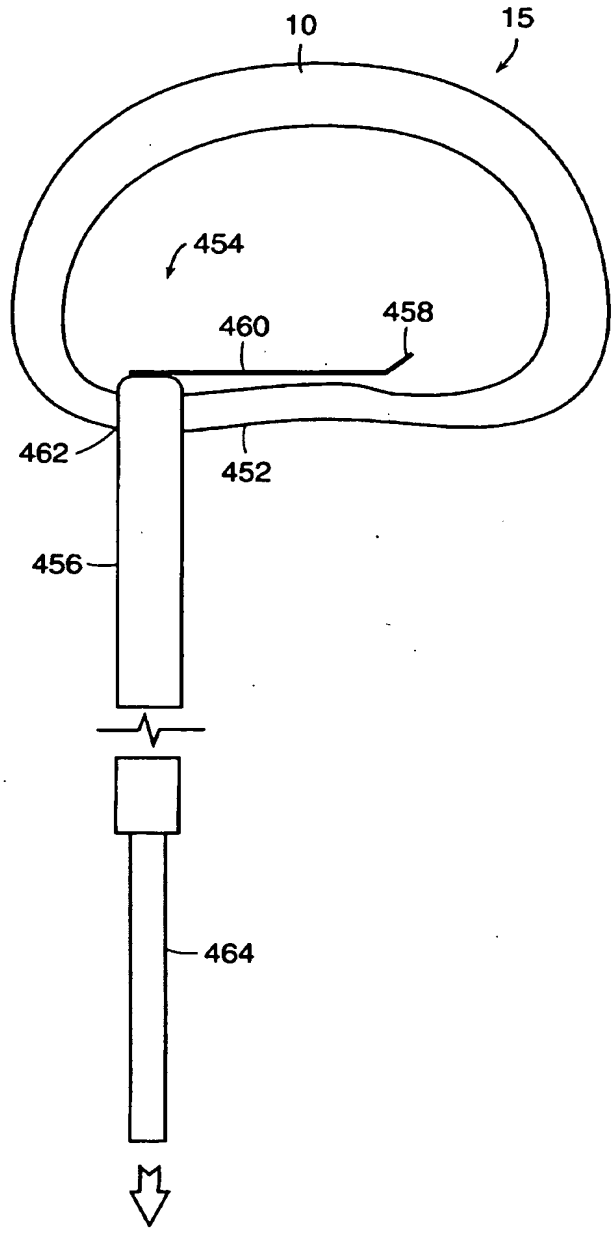

FIG. 58B

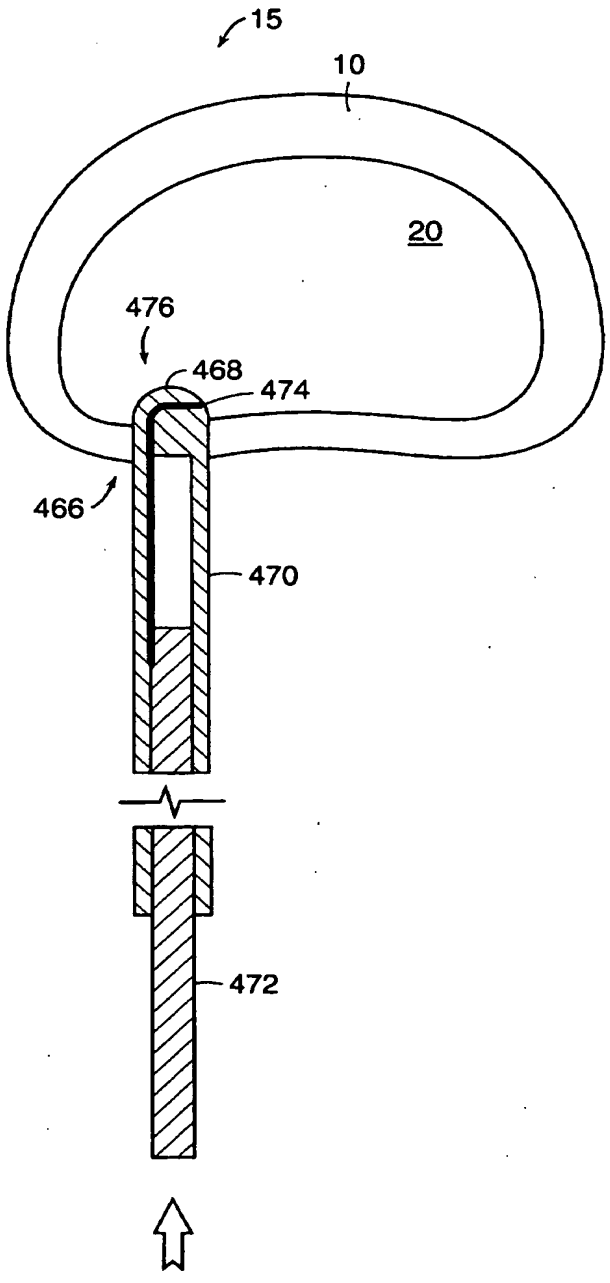

FIG. 59A

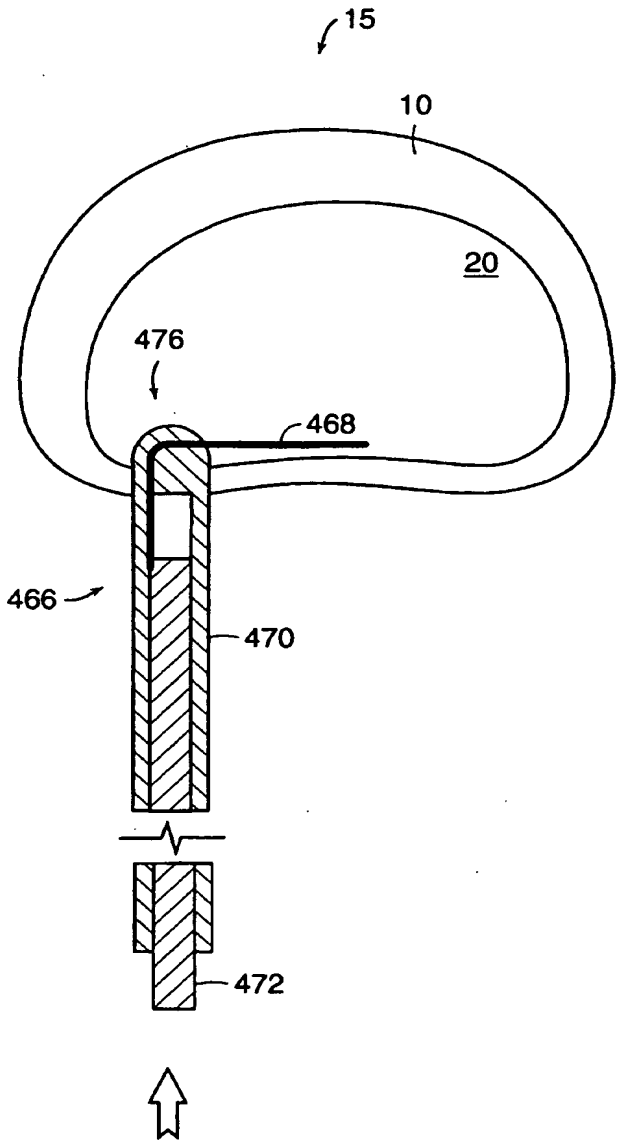

FIG. 59B

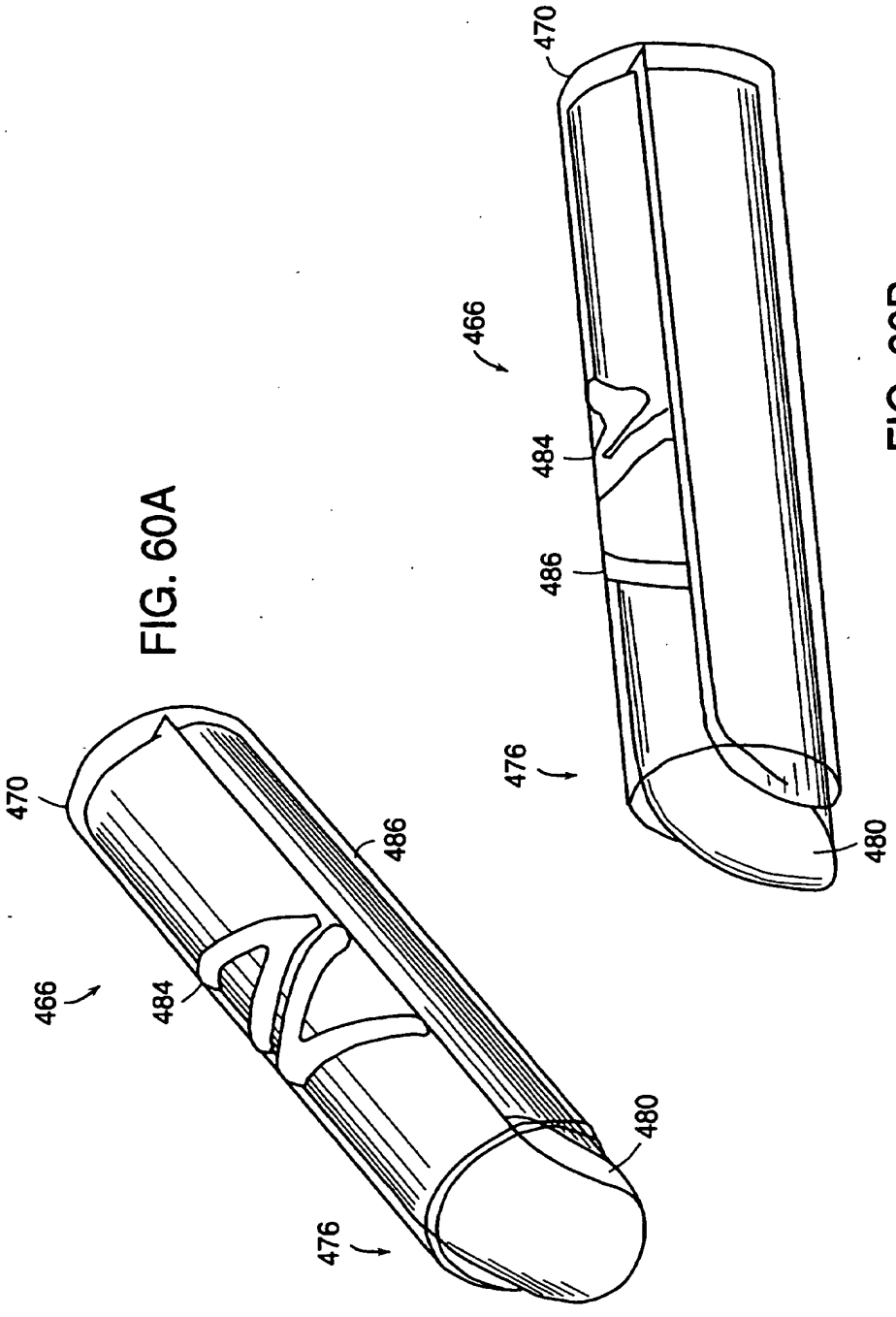

FIG. 60B

FIG. 60A

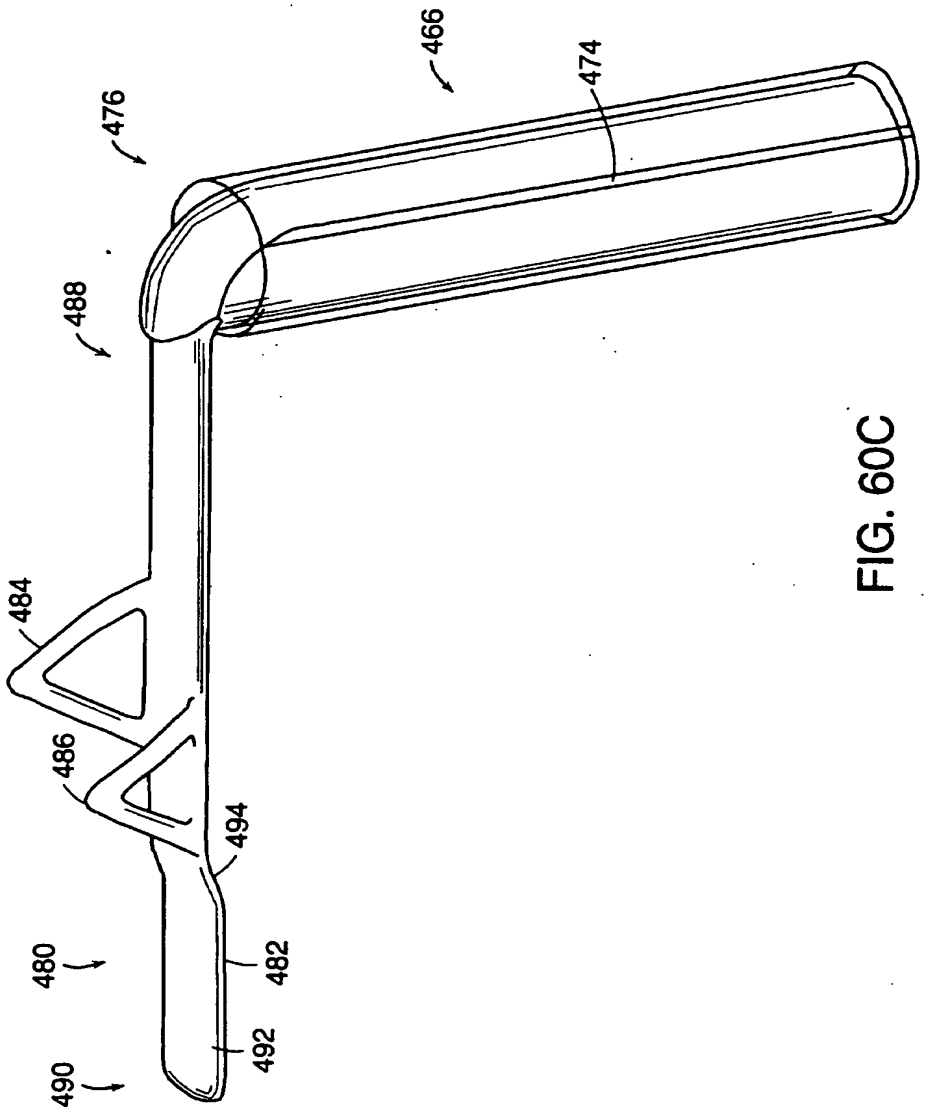

FIG. 60C

INTERNATIONAL SEARCH REPORT

Interr al Application No
PCT/US 00/22907

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/44

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 919 235 A (BAUMGARTNER WALTER ET AL) 6 July 1999 (1999-07-06) column 4, line 16 -column 6, line 26 ---	1-16, 60-62, 163-166
X	US 5 171 280 A (BAUMGARTNER WALTER) 15 December 1992 (1992-12-15) figures 7,8 column 3, line 32 - line 55 column 4, line 28 - line 29 column 4, line 30 - line 40 ---	1-16, 60-62, 163-166
X	EP 0 700 671 A (HOWMEDICA) 13 March 1996 (1996-03-13) column 11, line 45 -column 12, line 5 claim 1 figures 1-6 --- -/--	1

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
22 November 2000	30/11/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Mary, C

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Inter al Application No
PCT/US 00/22907

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	WO 00 42953 A (LAWSON KEVIN JON) 27 July 2000 (2000-07-27) figure 1 page 5, line 7 - line 20 page 5, line 34 -page 6, line 29	1

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 17-59,63-65,86-126,137,142-162,167-198

The present application contains 198 claims, 19 of them being independent claims.

The claims are arranged in such an inextricable manner that a reader must at first untangle the set of claims in order to guess which are the inventions for which protection is sought.

In view of the large number and also the wording of the claims presently on file, which render it difficult, if not impossible, to determine the matter for which protection is sought, the present application fails to comply with the clarity and conciseness requirements of Article 6 PCT (see also Rule 6.1(a) PCT) to such an extent that a meaningful search to all claims is impossible. Consequently, the search has been carried out for those parts which do appear to be clear and concise, namely claims 1-16, 60-62,163-166.

NB Although no formal objection concerning lack of unity of inventions has been raised, it would appear that at least 4 different groups of inventions are claimed, which are not so linked together as to form a single inventive concept.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inform d Application No
PCT/US 00/22907

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5919235 A	06-07-1999	EP 0773008 A	14-05-1997
		JP 9164156 A	24-06-1997
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